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HEARING ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S INVESTIGATION OF EPA'S EFFORTS TO PROTECT CHILDREN'S HEALTH

HEARING

BEFORE THE

COMMITTEE ON
ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

MARCH 17, 2010

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ONE HUNDRED ELEVENTH CONGRESS
SECOND SESSION

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HEARING ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S INVESTIGATION OF EPA'S EFFORTS TO PROTECT CHILDREN'S HEALTH

WEDNESDAY, MARCH 17, 2010

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, DC.

The full Committee met, pursuant to notice, at 10:30 a.m. in room 406, Dirksen Senate Office Building, Hon. Amy Klobuchar (acting Chairman of the full Committee) presiding.

Present: Senators Klobuchar, Lautenberg, Cardin, and Udall.

Also present: Senator Nelson.

OPENING STATEMENT OF HON. AMY KLOBUCHAR, U.S. SENATOR FROM THE STATE OF MINNESOTA

Senator KLOBUCHAR. I think we are ready to begin this hearing and convene this hearing.

I want to thank everyone for waiting. Senator Boxer is on her way. We had votes, as you know, so we appreciate everyone's patience. I know that Senator Boxer will be joining us, and I know that Senator Nelson is also. We are very honored to have him here with us.

I am the Chair of the Subcommittee on Children's Health, and as the mother of a 14-year-old, I am particularly interested in doing all that we can to protect and improve the health of our kids, especially when it comes to the environment. Every one of us has a stake in making sure kids grow up happy and healthy.

This is important not only for the well-being of our kids but also for our country. I know parents have an increasingly difficult job in today's world. The economic pressures, the time demands, and the many outside influences that affect our kids, all of these and more make it an especially challenging time for America's families.

Since I have entered the Senate I have made children's health one of my top priorities. Part of that was because I got involved when a little kid, a 4-year-old, swallowed a charm that he got with a pair of tennis shoes, and he ended up dying. He did not die from choking. He did not die from somehow that charm blocking his airways. He died because there was lead in that charm. When they tested it, it was 100 percent lead, and the lead in that charm went into his bloodstream, and he died over a period of days.

When you hear stories like that you know that things are not all right for the kids in this country. And that is why I worked with

Senator Pryor and others, and Senator Nelson on the Commerce Committee, to pass what the Wall Street Journal called the most sweeping consumer legislation in 16 years with the Children's Products Bill that we passed.

I have also worked with Senator Crapo on our formaldehyde bill. We now have many, many authors, I think nearly 20 authors, and it is heading to the floor. It went through the Committee. Again, formaldehyde in wood products is something that is not a partisan issue.

We are also looking at the effects of outdoor pollutants. With nearly 9 million kids in the United States affected by asthma, it is the leading serious chronic illness among our children. Outdoor air pollution worsens existing asthma.

Kids are already at greater risk from outdoor air pollution than healthy adults since kids have smaller airways than adults which are blocked easier, causing children to breathe more rapidly. According to the EPA, 66 percent of kids live in countries that exceed allowable levels of at least one of the principal air pollutants that cause or aggravate asthma. That not only affects our children's health, but it contributes to $3.2 billion in medical costs per year. And that was actually 66 percent of kids that live in counties that exceed rates.

We are also working in the Agriculture Committee to increase nutrition standards. That bill is actually being introduced today by Senator Lincoln and is something that will also be important as we go ahead for our children.

But more work must be done. I joined with Senator Boxer in requesting the GAO report that we will be hearing about today because we wanted to learn more about what EPA is doing to focus efforts on children's environmental health. With the increased prevalence of asthma, obesity, and chemical toxins, the agency should be focused on what steps we can take to prevent the spread and incidence of these risks but also researching long-term strategies to help improve the overall health of our children.

To develop an effective, focused strategy EPA must be working with other agencies, like the Department of Health and Human Services, to coordinate this effort. At one time, we had this coordination. In 1997 the President's Task Force on Children's Environmental Health and Safety Risks was authorized by Executive Order to provide this guidance and interagency coordination on children's environmental health. This task force ensured that agencies were working together on efforts to improve health and provided the type of commitment we need to ensure long-term goals to combat environmental risk.

That is why I am proud to introduce legislation, along with Senator Boxer, that would finally reestablish this task force. As a former prosecutor I know that the first responsibility of government is to protect our citizens. So we must do everything we can to make sure our Government is doing all that it can to protect our youngest citizens from environmental harm.

Ensuring that agencies are coordinating their efforts not only means that we can develop an effective strategy to improve the health of our kids, but it means that our Government can ensure that we are using taxpayer dollars effectively and not duplicating programs or working at cross purposes.

I look forward to hearing from out panelists about the GAO's findings and efforts to address the environmental health issues that are affecting our children. They are the most vulnerable among us, and it is our responsibility to protect them.

Our first witness, or more than that, expert, testifying today, I am pleased to see Senator Nelson here. He has been very active on this issue. I know that because I am on the Commerce Committee. And I thank him for coming today.

Senator Nelson.

OPENING STATEMENT OF HON. BILL NELSON, U.S. SENATOR FROM THE STATE OF FLORIDA

Senator NELSON. Thank you, Madam Chair.

Madam Chair, may I just talk to you and submit my comments for the record along with a number of letters from the people in the area affected?

Senator KLOBUCHAR. Without objection. Your comments will be put in the record.

Senator NELSON. Madam Chairman, we have an area west of West Palm Beach in Palm Beach County, Florida, called the Acreage. It is a residential area that has a rural character. There have been a number of children diagnosed with cancerous tumors, and all live within a radius of a couple of miles of each other.

Naturally, the consternation of not knowing if this is a cancer cluster has disrupted the lives of thousands of people who live in this area because now, with the fact that it might be a cancer cluster, you know what has happened to the value of homes, and you know what has happened to the ability to sell your home if someone has to move, with the fact that some people are so fearful that this is a cancer cluster have moved out and are renting elsewhere in the city, in the county, while still maintaining the mortgage on their home in this particular area.

This is an upscale area. It is on well water, and in this part of Florida these are shallow wells, and they are on septic tanks. So, the question is, what is the cause?

So, a year ago, when this came to my attention, I went to the Florida Department of Health. A part of them is the County Health Department. They are the ones to try to determine if this is a health hazard. And for almost a year now they have been studying this, and they cannot come up with any conclusions.

And so I am asking this Committee—and thank the Good Lord that you have got a Committee that is concerned that there might be these cancer clusters around the country—I am asking this Committee to bring the full weight of the expertise of the Federal Government to assist the first responders, which are the State Departments of Health, in determining if these are cancer clusters and if so, what we can do about it. And that means reaching out to the expertise of the EPA, the Environmental Protection Agency, as well as the Department of HHS and all of its myriad agencies including the CDC, the NCI, the NIH, et cetera.

Now, that is what we need, because these people are in a terrible situation, fearful for their health, but at the same time, because of no conclusions, paying a terrible price in not being able to move on with their lives.

In the testimony that I have submitted, and some of the letters that I have submitted, I have chronicled the specific cases of children that had these brain tumors. Now, is this something from the soil? Is this something from the shallow wells of the water? Is it particularly because children are the ones that get out and play in the dirt and crawl around on the floor and play in the puddles? We do not know. And we need to help bring about a resolution of information and conclusions.

Thank you, Madam Chair.

[The prepared statement of Senator Nelson follows:]

STATEMENT OF HON. BILL NELSON, U.S. SENATOR FROM THE STATE OF FLORIDA

Chairman Boxer, Ranking Member Inhofe and members of the Committee, thank you for the opportunity to testify before you today. Chairman Boxer, thank you for your continued leadership and actions to protect our Nation's children.

While the Committee examines the role of the Environmental Protection Agency and children's health I'd like to bring your attention to a community in Palm Beach, Florida, called the Acreage.

This town of about 50,000 has been shaken by fears of a cancer cluster. In February a study by the State health department found higher than normal incidences of brain and central nervous system cancer in girls and young women. Some residents have lost a loved one, others aren't sure if their homes are safe to live in, and if they try to leave, they worry they won't even be able to sell their homes.

Despite a year-long investigation, we still don't know what's causing these cancers, and people cannot get their lives back to normal until they have answers.

Last summer I asked the EPA and Centers for Disease Control to get involved and help the State and local health department in its investigation.

The Federal Government should take a larger and more proactive role in these complex and highly technical investigations because it has the expertise to lend a hand with detailed and sophisticated analysis.

EPA's mission is to protect human health and the environment. In order to fulfill that role and to help communities like the Acreage that are desperate for answers, the first step would be bringing the EPA and various agencies within the Department of Health and Human Services together to lay out a plan for what a Federal role should be in the investigation of cancer clusters.

I also believe the agencies, led by EPA and HHS, should prepare rapid response teams that will advise and assist not only the State and local health departments but help with communicating what's going on to the community. Here's why we need to act, and we need to do it immediately.

Jenna McCann died just 2 months before her 5th birthday because of a rare, aggressive form of brain cancer. A few years later her family learned of two other young girls with the same type of rare brain cancer who also lived in the Acreage.

Her mother, Kaye McCann, wrote to me, "How can a cancer that is so rare . . . affect 3 children living within just a few miles of each other in just a few years' time? I don't know what the answer is, but I know this area needs help."

Another mother, Jennifer Dunsford, was in the hospital waiting room while her 5-year-old son had to undergo brain surgery, and she started talking with another family in the waiting room. As it turned out, they also live in the Acreage. Their daughter had just had surgery because she also had brain cancer.

Later that same year, Jennifer found out there were two more children who lived in the Acreage who were diagnosed with brain cancer.

She was the resident in the Acreage who initiated the request for a study and who has even gone on the Dr. Oz show to tell people about what's happening in Florida and the need for more testing and for immediate help to find answers.

There are more stories like this, and with the consent of the Chairman I'd like to enter them into the hearing record.

Hearing stories like these is heartbreaking, and we've got to do something about it. I look forward to working with you on this.

[The referenced information follows:]

Letters from the Acreage

Dear Senator Nelson:

In 1997, my husband Thomas and I built our dream home in the Acreage after selling our home of 8.5 years in Dade County, Florida. Our home in the Acreage was to be the home I was to spend the rest of my life and retire comfortably in with my husband. We were married for 24 years.

In 2005, he had undergone a complete physical, including a nuclear heart test, a PSA prostate test, a complete blood work up and was declared perfectly healthy. He was told whatever it was he was doing, to keep doing it.

Eleven months later, he collapsed in the shower. Thomas was diagnosed with a glioblastoma multiforme stage 4 brain tumor, thyroid cancer and prostate cancer. My husband was not a smoker. Our doctors were convinced that he must have been exposed to something for three completely different and unrelated cancers to converge on him all at once. Because he was in such great health, he lived much longer than the three to six months the doctors thought he would live. He suffered and fought for his life for 28 long months. On September 26th, 2008, I lost my husband to brain cancer.

The long battle with these diseases drained us financially. Two weeks before the cancer cluster was announced, I put my house on the market. Because mortgage companies are no longer writing mortgages here due to the cluster designation, I cannot sell nor can I even rent this house. I never, in my wildest dreams, believed I would be living this nightmare.

Suffice to say, the issue in the Acreage has devastated all aspects of my life, personally and financially. I feel that had more federal assistance been available from the beginning of this being brought to the attention of the local authorities, there may have been a better outcome.

I want to thank you for testifying before the Senate Committee and being our voice in Washington, D.C. and raising awareness of what we as a community are experiencing in this untenable situation.

Respectfully submitted,

Joyce Gorring
13355 40th Lane North
Royal Palm Beach, FL 33411
(954) 812-1190

This journey really started for us in January of 2008. It was that month that we found out our then 5 year old son Garrett had a brain tumor. We were preparing for his brain surgery in February when we found out we would not be the only parents from the Acreage at Miami Children's Hospital. The DeCarlo family was there on February 18th patiently waiting as their 16 year old daughter Kristina was undergoing brain surgery. On February 20th Garrett had brain surgery – the DeCarlo family was there when we walked into the waiting area. We shared stories and compared where we lived - and we had an instant connection and instant camaraderie.

Then in April of 2008 my daughter came home from school and said a forth grade girl at her elementary school had just been diagnosed with a brain tumor and was rushed down to Miami Children's Hospital for surgery.

Fast forward to December of 2008 I received a phone call from Paulette DeCarlo – another teenage girl at the high school had to be air lifted to MCH – another brain tumor.

I talked with each of these families. I got their addresses and went to our Neurosurgeon at MCH (in May of 2009) and asked him what he thought I should do. We have four pediatric brain tumors diagnosed in 2008 (that we knew of) all living a few miles apart from one another – what should we do? He suggested I contact the Florida Department of Health and request an epidemiology study be conducted in our area.

So in late May 2009 I requested the study. I received an answer immediately from Dr. Sharon Watkins – a study would be done. My responsibility was to get a copy of the "Patient Listing Form" into the hands of as many cancer patients in the Acreage as possible. I started circulating an email with the form attached and it landed in the inbox of Tim Malloy. Tim started reporting on the story and that was the beginning of the media interest.

I have met almost all of the families who have a sick child or have lost a child to brain cancer. We have become family to one another. But there are so many more out there. The number of adults with brain tumors/cancers is almost four times the amount of the children – something has to be done. Not to mention rare cancers. Is it common to have a 13 year old girl with pancreatic cancer or a 17 year old girl with thyroid cancer?

My hope for this area is results, remediation and restoration. Without that this area and all who live here (whether they have or know a sick child/adult) will continue to suffer.

Sincerely,
Jennifer Dunsford

Dear Senator Nelson,

Thank you for staying on this difficult path we find ourselves on. You have supported us and watched over community as each new diagnosis was found. You tried to hold the DOH accountable to go forward with a Cancer Cluster study.

As you know my daughter Jessica Newfield was diagnosed at 11 years old. For months she presented with vomiting and headaches. we went to many doctors (pediatricians eye dr, psychiatrist) She was put on medication to help her sleep and help with behavior issues. Prylosec for vomiting (acid reflex they say) She attended therapy to try to control the up and downs of emotional out bursts.
Her grades were declining and I had to beg for help to get her special accommodations. Everyone thought she was just a over dramatic child with a mother on the verge of hysteria.

Finally one day after school when the headaches and nausea were so bad she was having double vision I asked for an MRI That was scheduled a week ahead. They squeezed us in. She was brave and went into the big scary loud machine. We then left to go home...Fifteen minutes later while on the road I was called by a doctor who told me to come back to the hospital right away that my daughter needed to be admitted with a large(orange size) mass on her brain.

Since than they were able to remove her tumor.Her recent MRI shows there could be reoccurrence of a new tumor. We are on a watch and wait.
In the last year I was connected with the Dunsford family to find a greater than expected number of children and adults in our area with this very rare disease.

Since being made aware of this It has been our goal to bring awareness to the signs and symptoms and maybe an environmental cause to our community.

We have not been welcomed with open arms. Cancer is a scary word and in this day in age especially brain cancer nobody what's to say it out load.
You have helped us bring awareness to a growing concern and to help everyone get on board to help us rule out our environmental and be able to stay in our homes peaceful happy and health...

Thank you for listening and in helping us fight this deadly disease.

Todd, Tracy Tyler and Jessica Taylor Newfield

Senator Nelson,

Our daughter, Jenna, was born July 2, 2001 a healthy little babygirl. In February 2005 at 3 1/2 years old Jenna was diagnosed with Stage 4 Ependymoblastoma, a rare, very aggressive form of brain cancer. We were told at that time that it was so rare it was grouped with other types of brain cancers (PNETs I believe is the term that was used). We were also told that it was very aggressive and had a high rate of reoccurrence. And when it did come back it came back with a vengeance. We were told the best place for her was Duke Children's Hospital. So Jenna and I moved to Durham, NC leaving my husband, 5 year old daughter and 5 month old son behind in Florida. Jenna underwent the most aggressive chemo treatment that could be given to her for 5 months and 2 months of radiation. Jenna and I came back to Florida in October 2005. Her cancer returned in December 2005, same place as before, approximately same size. Thedoctors said most likely it was growing while she was getting the radiation. We were also told by her doctor at Duke that he had not had a patient survive this cancer when it had come back that soon after treatment. I told him Jenna would be his first. The tumor was removed and she was put on another protocol with intravenous chemo and then oral chemo. Around the end of January 2006 the cancer came back and had spread to several parts of her brain. We were told then there was nothing else that could be done. Our little girl passed on May 19, 2006.

We had not heard of anyone else in the Acreage with brain tumors or cancers until June 2009. In 2008 another female child living in the acreage was diagnosed with Stage 1 Ependymo and late 2009 another female child was diagnosed with Stage 3 Ependymo. How can a cancer that is so rare that it's not tracked in its own group

affect 3 children living within just a few miles of each other in just a few years time?
I don't know what the answer is, but I know this area needs help. Whatever Jenna was exposed to that has caused this cluster my other two children and my husband and I have been exposed to. And everytime Tara and Jacob have headaches or complain of leg aches or arm/hand tingling I cringe. I don't panick, but my husband and I look for other signs. The scary part, though, is by the time "other signs" present themselves it could be too late.

You have been on our side since the beginning of this and my husband and I appreciate it. I will never forget something you said when you came to Wellington Hospital and met with us as a community and heard each of our stories. You looked at the representatives from the PB County Health Department and said if it was one of "our children" being affected we would want some answers (that's not verbatim, but it's close enough).

I appreciate the recent efforts of Florida's DEP with the water, soil & gamma testings. I don't know if the cause will ever be found, but I know in my heart that 3 Ependymos in an area our size in a few years time is not a coincidence. And most of the other brain cancers that have affected the Acreage are not the more common brain cancers - and that is not a coincidence.

I'm not sure what else can be said. Except that this has changed our lives forever. And no one is safe in the Acreage until it's found out what has caused the cancers and the area is either cleaned up or condemned.

Kaye and David McCann

PS - I'm attaching a couple of pictures of Jenna. Maybe putting a face to this cause will help as well! The stats used to consider the Acreage a pediatric cancer cluster was 3 female pediatrics from - 2007. If these stats are correct, then Jenna is one of those three - a # to so many, but a daughter, sister, granddaughter, niece, great niece, cousin, friend to those of us who knew and loved her so much!

Senator KLOBUCHAR. Thank you very much, Senator Nelson. We really appreciate that, and hopefully we can get to the bottom of this.

Senator Cardin.

OPENING STATEMENT OF HON. BENJAMIN L. CARDIN, U.S. SENATOR FROM THE STATE OF MARYLAND

Senator CARDIN. Well, Senator Klobuchar, Chairman Klobuchar, thank you very much for conducting this hearing on the Government Accountability Office's investigation of EPA's effort to protect children's health.

Let me use a little bit of my time in opening statement to introduce a witness that will be on our second panel, Dr. Cynthia Bearer. We welcome you to the Committee from the University of Maryland Medical Center in Baltimore City. She is the Cobey Professor of Neonatology and Chief of the University of Maryland Medical Center Hospital for Children Division of Neonatology.

Dr. Bearer is here today on behalf of the Children's Environmental Health Network for which she serves as the Board Chairman. The Network is the national organization whose mission it is to protect children from environmental health hazards and to work to build a healthier environment for kids to grow in.

We certainly welcome you here, and we look forward to your testimony. I apologize. I will be running in and out because of other duties today. But thank you for appearing before our Committee.

Let me just point out generally, Madam Chair, if I might, the importance of this subject. We know that children are more vulnerable to the environmental risks. We know that their bodies cannot detoxify at the same efficiency as older bodies can. We also know, as Senator Nelson pointed out, children are closer to the ground. Therefore, they are crawling around and are more vulnerable to the environmental risk factors.

We also know that they eat and breathe more per body weight than adults do. So, in 1993 the National Academy of Science came to the conclusion that children are not little adults and therefore are more vulnerable to these environmental risks.

I was pleased in 1997 that the EPA established the Office of Children's Health as well as the advisory committee to implement and oversee a national plan to protect our children from environmental exposures. A major undertaking of the EPA is participation in the National Children's Study authorized by Congress in 2000. The National Children's Study examines the effects of environmental influences on the health of 100,000 children across the United States, following them from before birth to age 21.

Health disparities are also affected by environmental factors with environmental health risks affecting minority and low income children disproportionately because of the demographic trends in the United States, according to the Interagency Forum of Child and Family Statistics. To this end it is particularly important to conduct research on children that will include racial and ethnic majorities, minorities, excuse me.

There is one finding, Madam Chair, that I know, that provoked, I think, this hearing, and that is EPA has not updated its National Agenda regarding protecting children's health in over 10 years and that the recent 2009 goals do not include the Office of Children's Health as a target area for improvement.

This hearing is very important. Our children are our most precious assets. We say it over and over again; we want to do everything we can to protect them. They do not have the same advocacy as the adult community has. And yet, as Senator Nelson pointed out in his specific example, they are extremely vulnerable to environmental risk.

The Environmental Protection Agency must have a focus on what we do to protect our children from these environmental risks. The study is an important part that they are participating with on other, with other agencies. It is also important that we update the strategies on a regular basis. I think this hearing is an appropriate oversight for our Committee, and I thank the Chair for conducting it.

And with that I would yield back the balance of my time.

Senator KLOBUCHAR. Thank you very much, Senator Cardin.

Senator Lautenberg.

OPENING STATEMENT OF HON. FRANK R. LAUTENBERG, U.S. SENATOR FROM THE STATE OF NEW JERSEY

Senator LAUTENBERG. Thanks, Madam Chairman, for having this hearing.

Each of us who has a grandchild is immediately an expert on children's health, and the concerns that we have for them rise to the top of our agenda. I am fortunate enough to have four kids and am grandfather of 11 between my wife and me. This subject is a crucial one for us.

I see in my own family, I have a grandson who is 16 who has got asthma and a granddaughter who is 11 who has diabetes. We, in order to help them, I am determined, and I think we all are, to make sure that we do everything for grandchildren across our country.

That is why in 1997 President Clinton issued an Executive Order to protect infants and children from environmental health risks, and the Administrator of the EPA created the Office of Children's Health. That office developed into a powerful force that consistently fought for the well-being of our Nation's children. The nature of children's health was a top priority of EPA research budgets and policies.

The office also made sure that children's health was a priority factor when the agency created cancer guidelines, environmental toxin guidelines, in its data base on chemical risks.

Unfortunately, the progress made to safeguard children's health ground to a halt during the Bush administration as today's report from the Government Accountability Office makes clear. The EPA seemed to develop collective amnesia, lost focus on children's health issues, and the Office of Children's Health withered on the vine.

In fact, the Administrator of the EPA office showed such little interest in the office that it went without a permanent director for 6 years. And as today's GAO report concludes, the Office of Children's Health, and here I quote, declined in the absence of direct and meaningful support from the EPA's Administrator.

The good news is that things have turned around with Administrator Lisa Jackson at the helm of EPA. She has recommitted the Agency to protecting children from environmental dangers, moved quickly to appoint Peter Grevatt—we welcome him here—as the new Director of the Office of Children's Health, and made him a key advisor on her team.

Soon after his appointment Director Grevatt issued a roadmap with five clear priorities to protect children's health. And I was pleased that he made the reform of toxics, the Toxic Substance Control Act, known as TSCA, a top priority. Right now TSCA is not up to the task of protecting our kids from toxic chemicals, and it has got to be overhauled so we can figure out what chemicals children are exposed to and what exactly we need to do to protect them.

Children, as was said, are not simply small adults. They are extremely vulnerable to the acute dangers of toxic chemicals. And according to a report by the Safer Chemicals, Healthy Families Coalition as much as 5 percent of cancers, 10 percent of neural behavioral disorders and 30 percent of asthma cases in children are associated with toxic chemicals.

I do not know whether a report—the Op Ed piece by Nicholas Kristof, written in the New York Times, where he raised the question of toxics and autism. It got a lot of attention, and we are going to be focused in that area, thank goodness.

So, we are here today because more work has to be done when it comes to children's health. Unfortunately, I, too, am called to other places. Madam Chairman, this is an important Committee and an important hearing, and I am sure that we will establish a good record from which we can work.

Thank you very much. And thank you to the witnesses.

Senator KLOBUCHAR. Thank you very much, Senator.

And now we are going to move to our first panel. If you could come forward, I will introduce you.

OK, well thank you for being here today. We have two panelists for our first panel. The first is Dr. Peter Grevatt, who is the Director of the Office of Children's Health Protection with the EPA, and the second is John Stephenson, who is the Director of Natural Resources and Environment with the Government Accountability Office or, as we know them, the GAO.

So, we will start with Director Grevatt.

STATEMENT OF PETER GREVATT, PH.D., DIRECTOR, OFFICE OF CHILDREN'S HEALTH PROTECTION AND ENVIRONMENTAL EDUCATION, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. GREVATT. Good morning, Madam Chairman and members of the Committee.

My name is Peter Grevatt, and I am the Director of the Office of Children's Health Protection and Environmental Education at the U.S. Environmental Protection Agency. Thank you for the opportunity to appear before this Committee to discuss EPA's efforts to improve children's health.

Children face greater threats from environmental pollutants than adults due to differences in their physiology, activity patterns and development. And not all children are the same. We continue to see disparities in exposures and health outcomes among the poor, African American, Latino, Native American and other ethnic minorities.

Children's health is a driving force behind Administrator Jackson's priorities. In February, in a memo to EPA's senior managers, she reaffirmed EPA's commitment to considering the health of pregnant women, infants and children in all human health related activities and to the use of EPA's policy on evaluating health risks to children and the best available research and data to guide our children's health protection efforts.

In the memo Administrator Jackson describes EPA's children's health agenda and identifies my office, the Office of Children's Health Protection, as having the lead in ensuring that the agency is successful in its efforts to protect children's health.

EPA agrees that the GAO report reflects the progress of the agency's children's health protection efforts, accurately portrays the agencies challenges in addressing children's environmental health, and sets forth sound recommendations on steps that could be taken to better incorporate protection of children's health as an integral part of EPA's everyday business.

EPA is implementing a comprehensive strategy to ensure protection of children's environmental health which embodies the five key priorities I previously discussed for children's environmental health at EPA.

EPA will use the best science to ensure that regulations provide for protection of children's environmental health by actively addressing the potential for unique childhood vulnerability and exposure. Our goal is to reduce negative environmental health impacts on children through rulemaking, policy, enforcement and research that focus on prenatal and childhood vulnerabilities.

For example EPA is confronting the harmful effects of criteria air pollutants on the health of children. We have decided to reconsider the 2008 National Smog Standards to ensure that they are scientifically sound and protective of human health. We will bring the best science to bear in our decisions.

The Children's Environmental Health Centers, established in 1998 by EPA and the National Institute of Environmental Health Sciences, examined the interactions between key environmental exposures in a range of child health outcomes such as growth and development, asthma and autism, with the goals of preventing and reducing childhood diseases and translating the findings to the effected communities and the broader public.

Assuring the safety of chemicals in our products and our environment is critical to ensure the health of children. EPA will establish standards, policies and guidance to help eliminate harmful prenatal and childhood exposures to pesticides and other toxic chemicals.

And last year Administrator Jackson announced principles for modernizing the Toxic Substances Control Act, or TSCA. We are hopeful that TSCA will be updated by Congress so that we are better able to take action on chemicals that pose a concern, particularly those that affect children.

Separately, we are shifting EPA's focus to address high concern chemicals and filling data gaps on widely produced chemicals. At the end of 2009 we released our first ever Chemical Action Plans for four groups of substances, and more plans are in the pipelines for 2010.

EPA also recognizes that children may be more vulnerable to pesticide exposure. We are planning to further strengthen assessment of pesticide health risks. By modifying our risk assessment approach we hope to continue to minimize the adverse health consequences of pesticide exposures. We are also working closely with partners such as the Department of Housing and Urban Development and the Centers for Disease Control and Protection—and Prevention, excuse me—to protect children from pesticides in residences and in schools.

We will coordinate national and international community based programs to eliminate threats to children's health. EPA is collaborating with the Department of Health and Human Services, Department of Education and a diverse group of stakeholders through our Children's Health Protection Advisory Committee to provide tools to communities to build a new generation of healthy green schools and help ensure that existing schools are in good condition and are properly maintained.

EPA, HHS and the Department of Housing and Urban Development are also collaborating to respond to the Surgeon General's call to action on healthy homes by taking advantages of opportunities to leverage Federal resources to provide States, tribes and local communities with the necessary tools to help improve home environments, particularly in underserved communities.

EPA and HHS are also joining with other Federal departments and agencies to work toward reestablishing the President's Task Force on Environmental Health Risks and Safety Risks to Children. And with this group we will collaborate to address the most critical children's environmental health issues facing the Nation.

EPA is also working with other Federal agencies to address environmental factors that contribute to the pervasive problem of obesity in children through our participation in the Task Force on Childhood Obesity.

As part of our efforts in all of these areas, we will utilize our Children's Health Protection Advisory Committee to help ensure that we are developing effective strategies to address the most significant threats to children's environmental health.

Thank you, Chairman Boxer, and Chairman Klobuchar and Members of this Committee, for the opportunity to talk to you today. As evident by our strategy and actions Administrator Jackson and I share your commitment to children's environmental health, and we appreciate your ongoing interest in our efforts.

Thank you again for inviting me to give testimony, and I look forward to answering any questions you may have.

[The prepared statement of Mr. Grevatt follows:]

TESTIMONY OF PETER GREVATT, PhD

DIRECTOR OF THE OFFICE OF CHILDREN'S HEALTH PROTECTION AND
ENVIRONMENTAL EDUCATION
U.S. ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
UNITED STATES SENATE

March 17, 2010

Chairman Boxer, Ranking Member Inhofe, and Members of the Committee, thank you for the opportunity to appear before this committee to discuss EPA's efforts to improve children's health.

Children's health is a driving force behind Administrator Jackson's priorities. In a February 2010 memo to EPA senior managers, she reaffirmed EPA's commitment to considering the health of pregnant women, infants and children in all human health related activities and to the use of EPA's 1995 Policy on Evaluating Health Risks to Children and the best available research and data to guide our children's health protection efforts. In the memo, Administrator Jackson describes EPA's Children's Health Agenda and identifies the Office of Children's Health Protection as having the lead in ensuring that the Agency is successful in its efforts to protect children's health.

Why Focus on Children?

EPA's mission is to protect human health and the environment. Ensuring that our children are protected from exposure to environmental threats is central to EPA's work. Children face greater threats from environmental pollutants than adults due to differences in their physiology, activity patterns and development. And not all children are the same: we continue to see disparities in exposures and health outcomes among the poor, African American, Latino, Native American and other ethnic minorities. [1]

Children eat, drink and breathe more per pound than adults. When food, water, or air is polluted, children are exposed to more of the pollution than adults. For example, an average infant less than 6 months old consumes 2.5 times more water than an adult on a per pound basis. [2]

Children can have greater exposure to chemicals through behaviors that are unique to childhood, such as crawling, putting objects in their mouths, and eating nonfood items. Children also have unique exposures, for example, through the umbilical cord and through breast milk. Their bodies are rapidly developing. Exposure to toxic chemicals during critical windows of development can lead to disease or other serious effects on organ systems.[3]

Children's rapid development during pregnancy and childhood may also increase their vulnerabilities to toxicants. For example, the nervous system begins to rapidly develop in the embryo only days after conception and continues to develop through puberty. Depending upon the toxicant, early exposures may have serious consequences throughout a child's life.

Administrator Jackson recently began a new era of focus on communities historically underrepresented in EPA decision making. EPA will build strong working relationships with tribes, communities of color, and economically distressed cities and towns, and we will include children's environmental health and environmental justice principles in all of our decisions.

Report from General Accounting Office

GAO was asked by this committee to determine the extent to which EPA has institutionalized and prioritized the protection of children's health from environmental risks.

EPA agrees that the GAO report reflects well the early history and progress of the Agency's children's health protection efforts. The report accurately portrays the Agency's challenges in addressing children's environmental health, and sets forth sound recommendations on steps that could be taken to better incorporate protection of children's health as an integral part of EPA's everyday business.

Administrator Jackson noted in a September 2009 memo that "...several goals central to the environmental mission of this Administration need to be brought into the regulatory process as early as possible in order to give them the attention they are due; these are environmental justice, children's health, and climate change....With respect to children's health, early attention to this issue is critical to grasping the full implications of a regulatory or policy decision for children and to addressing those implications in the decision making process."

Offices throughout the Agency continue to work to protect children's health by implementing mandates, developing regulations, supporting programs, reaching out to communities, and funding and conducting research. GAO's recommendations will help EPA to strengthen these efforts to bring about even more tangible results.

EPA and the Department of Health and Human Services (HHS) are joining with other federal departments and agencies to work towards reestablishing the President's Task Force on Environmental Health Risks and Safety Risks to Children, and with this group we will collaborate to address the most critical children's environmental health issues facing the Nation. Through our participation in the President's Task Force on Childhood Obesity, EPA is also working with other federal agencies to address environmental factors that contribute to the pervasive problem of obesity in children.

Administrator Jackson has made clear that children's environmental health will be a top priority for EPA under her leadership and we are in the process of implementing a comprehensive strategy to ensure protection of children's environmental health at EPA.

EPA's strategy on children's health

1. **EPA will use the best science to ensure that regulations provide for protection of children's environmental health by actively addressing the potential for unique childhood vulnerability and exposure.** Our goal is to reduce negative environmental health impacts on children through rulemaking, policy, enforcement and research that focus on prenatal and childhood vulnerabilities.

National Ambient Air Quality Standards (NAAQS): EPA is confronting the harmful effects of criteria pollutants on the health of children. For example, we have decided to reconsider the 2008 national smog standards to ensure they are scientifically sound and protective of human health. Smog, which is also known as ground level ozone, has been linked to asthma and other respiratory illnesses in children. "This is one of the most important protection measures we can take to safeguard our health and our environment. Smog in the air can cause difficulty breathing and aggravate asthma, especially in children," said EPA Administrator Lisa P. Jackson. "Reconsidering these standards and ensuring acceptable levels of ground level ozone could cut health care costs and make our cities healthier, safer places to live, work and play."

EPA has enhanced its **Rule and Policy Information Development System** (RAPIDS) to collect more targeted information regarding effects on children's health. Specifically, programs are now asked to provide information on whether a rule is likely to address an adverse impact on childhood life stages and the nature of that impact.

America's Children and the Environment: EPA is developing appropriate indicators of its efforts in protecting children's health. *America's Children and the Environment* brings together quantitative information from a variety of sources to show trends in levels of environmental contaminants in air, water, food, and soil; concentrations of contaminants measured in the bodies of mothers and children; and childhood diseases that may be influenced by environmental factors.

The report presents indicators of key factors relevant to the environment and children in the United States; informs discussions among policymakers and the public about how to improve federal data on children and the environment; and helps policymakers and the public track and understand the potential impacts of environmental contaminants on children's health and, ultimately, to identify and evaluate ways to minimize environmental impacts on children.

EPA's America's Children and the Environment website is updated annually with the most current data available for our indicators of contaminants, body burdens and illnesses related to environmental exposures in children. The website presents data for 21 different indicators of children's environmental health, including measures for drinking water contaminants, blood mercury levels, and neurodevelopmental disorders. The next update to the website will take place this summer. We have also started working on developing several new indicators to represent additional children's environmental health topics. We obtained input from the Children's Health Protection Advisory Committee on our selection of new topics and data sets, and plan to publish an updated edition of America's Children and the Environment in 2011.

In addition, EPA is a partner in the development of the federal government wide *America's Children Report*.

Children's Environmental Health Centers: The Children's Environmental Health Centers, established in 1998 by HHS's National Institute of Environmental Health Sciences (NIEHS) and EPA, examine the interactions between key environmental exposures and a range of child health outcomes, including overall growth and development, asthma and respiratory health and neurodevelopmental disorders such as autism. Collectively, these centers comprise a national network of scientific and community leaders, health care providers, and government officials with the common goals of preventing and reducing childhood diseases in the research areas under study and translating the findings to the affected communities and the broader public.

The Children's Environmental Health Centers have evolved over the past ten years to emphasize a multidisciplinary approach that includes basic, applied, and community based participatory research. EPA will use research results from the children's centers to develop more robust protections for children's environmental health.

National Children's Study: The National Children's Study is the largest ever study of children's health in the US and is expected to examine the development of 100,000 children from before birth to age 21. Of high relevance to EPA, the study will eventually provide data for investigating the effects of environmental exposures (chemical, biological, physical, and psychosocial) as well as gene-environment interactions on pregnancy outcomes, child health and development, and precursors of adult disease.

By studying the same children over time through their different phases of growth and development, including early life exposures, we hope to be able to better understand the role of environmental factors in health and disease. The study is expected to provide data that will play an important role in helping EPA establish policies that are based on science and protective of children's health. Household and community level environmental measures analyzed together with biological indicators will help us identify health risk factors across multiple life stages.

The data generated from these activities are expected to directly inform interventions for EPA, public health stakeholders, manufacturers, designers and builders. Data from the National Children's Study are also expected to help EPA evaluate the consequences and the effectiveness of our regulatory decisions.

2. Protecting children through safe chemicals management.

The **Toxic Substances Control Act** (TSCA) Inventory currently contains over 80,000 existing chemicals, few of which have been studied for their risks to children. Assuring the safety of chemicals in our products, our environment and our bodies is critical to ensure the health of children. EPA will consider establishing standards, policies, and guidance at home and abroad to help eliminate harmful prenatal and childhood exposures to pesticides and other toxic chemicals.

Unlike the laws applicable to drugs and pesticides, TSCA does not have a mandatory review program for EPA to determine the safety of existing chemicals. In addition, TSCA places legal and procedural requirements on EPA before the Agency can request the generation and submission of health and environmental effects data on existing chemicals. It has also proven difficult in some cases to take action to limit or ban chemicals found to cause unreasonable risks to human health or the environment.

There is growing interest in the United States to modernize TSCA. Last year Administrator Jackson announced principles for modernizing the Toxic Substances Control Act. We are hopeful that TSCA will be updated by Congress so that we are better able to take action on chemicals that pose a concern, particularly those that adversely affect children. Separately, EPA is shifting its focus to address chemicals that pose a concern to the public. At the end of 2009, EPA's Office of Prevention, Pesticides and Toxic Substances released an initial set of chemical action plans for four groups of substances, and more plans are in the pipeline for 2010.

Pesticides: EPA also recognizes that children may be more vulnerable to pesticide exposure and, under the Food Quality Protection Act of 1996 (FQPA), EPA is required to consider an extra margin of safety to protect children when regulating pesticides. Over a 10 year period, EPA reevaluated all food use pesticides to ensure that they were protective and eliminated uses where risks exceeded our level of concern. For example, indoor uses of chlorpyrifos and diazinon were largely eliminated, as well as use of those pesticides on residential lawns based in part on potential risks to children. Many food uses of methyl parathion were eliminated for that reason.

EPA has taken steps to protect children from pesticide risks in addition to increasing safety factors in risk assessments and improving risk management decisions. We are working closely with partners such as the Department of Housing and Urban Development (HUD) and, in HHS, the Centers for Disease Control and Prevention and the Administration for Children and Families, to protect children from pesticides in residences and in schools. EPA developed a Pest Management Strategic Plan for School Integrated Pest Management (IPM) and as part of our Healthy Homes Initiative, developed a comprehensive IPM in Housing Strategy designed to make IPM standard practice in affordable housing nationwide. We are conducting public education campaigns on the safe storage of pesticides, use of pesticides in child care centers, and the importance of following pesticide labels.

We are also planning to further strengthen assessment of pesticide health risks. EPA has taken public comment on a proposed approach that would include a more thorough assessment of risks to workers, including farmworkers and farm children, as well as risks posed by pesticides that are not used on food. Under the proposal, EPA risk assessments for children and farmworkers, would consider aggregate pesticide exposures from all sources in addition to cumulative effects from multiple pesticides that have similar toxicity. EPA also would apply an additional safety factor to protect infants and children from the risks of pesticides where the available data are incomplete. By modifying our risk assessment approach, we hope to continue to minimize the adverse health consequences of pesticide exposure.

3. Coordinate national and international community based programs to eliminate threats to children's health while measuring and communicating our progress.

Healthy School Environments: The Energy Independence and Security Act directed EPA to develop guidelines for healthy, high performing schools. Healthy schools provide a clean, safe, and energy efficient learning environment, encourage physical exercise through multiple transportation choices such as biking and walking, and reduce the need for additional buildings and facilities by sharing recreational and other facilities with the broader community.

EPA is collaborating with HHS, the Department of Education and a diverse group of stakeholders, through our Children's Health Protection Advisory Committee, to develop guidelines to help states and communities make better decisions with respect to where new schools are located. We will receive a report from the Advisory Committee in April, and we expect to release a draft for public review in the Fall. Guidelines will provide tools to communities to build a new generation of healthy green schools, and will ensure that existing schools are in good condition and properly maintained.

Healthy Homes: Children spend more time in their homes than in any other environment, and are at greater risk from environmental hazards in the home than adults. Exposure to lead-based paints and other environmental hazards in the home disproportionately impact children, the poor, and minorities.

According to HUD's 2007 American Housing Survey, nearly 6 million households live with moderate or severe physical housing problems. About 24 million homes face significant lead-based paint hazards.

As stated in the Surgeon General's Call to Action to Promote Healthy Homes, "Residents of homes with significant upkeep problems and structural and safety defects, such as lack of specific safety devices, deferred maintenance, moisture, and pest infestation, are also at increased risk for housing related illness, injury, and disability".[4] Housing related health costs total in the billions annually. Examples of housing related health hazards include lead based paint, radon, and other toxins in the environment. [5] Depending upon exposure levels, housing related hazards may cause lead poisoning, cancer, and neurobehavioral disorders.

EPA, HHS and HUD are collaborating to respond to the Surgeon General's Call to Action on healthy homes[6] by taking advantage of opportunities to leverage federal resources to provide states, Tribes and local communities with the necessary tools to help improve home environments, particularly in underserved communities.

Pediatric Environmental Health Specialty Units: With HHS's Agency for Toxic Substances and Disease Registry, EPA supports the Pediatric Environmental Health Specialty Units, a program that provides advice to communities, healthcare providers, and parents on children's environmental health issues. The Units bring together many disciplines, such as occupational and environmental health physicians, pediatric practitioners, medical toxicologists, nurses and other specialists. These experts in environmental exposures work to prevent, diagnose, manage and treat environmentally driven health issues in children. They are located in hospitals in each of the ten EPA regional offices, and this model is being utilized in other countries as well. The Units assist primary health care professionals in a wide range of exposures such as lead, arsenic, carbon monoxide, pesticides, air pollutants, mold, waterborne contaminants, toxic waste, agricultural pollution and household chemicals. They also assist in site specific cases, such as school and day care environments; deal with diagnostic dilemmas, where the etiology of problems are possibly environmental in nature; and educate health care providers and the general public about children's health issues related to exposure to environmental contaminants. Parents and other public health professionals often enlist the aid of the Units directly.

Environmental Health Disparities: Two critically important environmental health issues -- childhood asthma and lead exposure -- demonstrate an inequality in exposures and health effects for some of America's children. For example, one study indicates that children who belong to racial or ethnic minorities often have greater harmful exposures and poorer health outcomes than white children.[7] Improving the environment and public health for all necessitates a special focus on health disparities and their causes.

Asthma: Asthma is a chronic disease affecting about 6.8 million children in the United States.[8] It is a major reason for emergency room and hospital visits and missed school days. The burdens of asthma fall more heavily on African American and Puerto Rican children.[9] In 2004 to 2007, 13% of African American children, regardless of family income, had asthma.[10] This compares to 8% of White, 7% of Mexican-Americans, 20% of Puerto Rican children, and 10% of American Indian and Alaskan Native children.[11]

Children may inherit a tendency to develop asthma, and racial and ethnic differences in the burden of asthma may be related to social and economic status, access to health care, and exposure to environmental triggers.[12] Asthma rates have increased worldwide.[13] The US rate increased 75% from 1980 to 1994. In 2005, 12.7% of children had been diagnosed with asthma at some point in their lifetime.[14] The largest increase was among children up to 4 years old (160%). Rates among children 5 to 14 years old increased by 74%.[15] Although asthma rates have stabilized, a 2005 study showed that childhood asthma rates remain at an all time high.[16]

For the period 1980-2005, increases in asthma rates among poor minorities have been even larger than the averages.[17] EPA's policies to address asthma take minority children into special consideration. The EPA Asthma Initiative,[18] which was originally set forth in the 1999 Asthma

Strategy developed by the President's Task Force on Environmental Health Risks and Safety Risks to Children, includes research, education and outreach to identify the environmental factors that cause asthma and asthma symptoms, and to replicate effective interventions to mitigate these factors in homes and schools.

EPA sponsored the Asthma Health Outcomes Project—a 2006 study showing that asthma programs that address environmental triggers work best to improve health outcomes, such as reduced emergency room visits, improved quality of life, and fewer missed days of school or work, when they build strong connections with front-line health care providers and local communities.[19]

In response, we launched the Communities in Action for Asthma Friendly Environments initiative in 2005-2006. This initiative creates a network of community programs, nearly 500, pursuing strategies to achieve positive health outcomes, including cultivating program leaders, establishing sound community relationships, maximizing cooperative opportunities, providing integrated health care services and implementing tailored environmental interventions.

Leading programs in the Network are realizing 50-80% reductions in emergency department visits and hospitalizations, based on each program's tracking studies. These programs track outcomes for their enrolled patients -- in general, they compare outcome endpoints at 12 months to baseline at time of enrollment.[20]

Lead: It is often recognized that the removal of lead from gasoline and resulting lowered blood lead levels in children is a public health success story. The average concentration of lead in the blood of children 5 years old and under dropped from 15 micrograms per deciliter (μg/dL) in 1976-1980 to 1.4 μg/dL in 1999-2004, a decline of 91%.[21] Lead also has been eliminated or reduced in paint, drinking water, food and beverage containers and ceramic ware, and in products such as toys, mini blinds, and playground equipment. The lead strategy developed in 2000 by the President's Task Force on Environmental Health Risks and Safety Risks to Children was instrumental in furthering reductions of blood lead in America's children.

Although this decline in elevated blood lead levels is heartening and has been seen among all ethnic groups, lead levels continue to be highest among African American children, whose median blood lead level remains significantly above that of other children.[22] From 1999-2004, some 285,000 children aged 1–5 were estimated to have elevated blood lead levels each year; 33% of these were Black children.[23] Residence in older housing, poverty, age, and being non-Hispanic black are still major risk factors for higher lead levels.[24] This is also seen on a community wide level; one inner city prevalence study published in 2004 found that 27% of children in two inner city Chicago communities had elevated blood lead levels.[25]

As part of an effort to address new cases of elevated blood lead levels arising as a result of renovation and repair work, in 2008, EPA issued an additional rule aimed at protecting children from lead paint hazards. The Lead Renovation, Repair and Painting Rule (40 CFR Part 745) provides broad protections against inadvertent lead poisoning by requiring contractors and construction professionals to be trained, certified and to use lead safe work practices during renovation, repair and painting in pre-1978 housing and childcare centers. The rule also requires contractors to provide an important lead hazard information brochure to property owners, tenants, and owners and operators of buildings that have child occupied facilities as well as to the parents and guardians of children under age six using the facilities.

The rule will be fully effective in April 2010. In addition, last August EPA announced plans to propose further strengthening and expanding the scope of these regulations.

Sustainable Communities: Our work at EPA extends beyond protecting the natural environment. These days, more and more we're talking about the built environment. And our focus is not just on how human activities affect the environment. It's about how the environment we have created in our towns and cities and communities where we live can affect our health and well being. Chronic diseases such as diabetes and asthma are influenced by environmental conditions. In low income communities children are often at greatest risk from exposure to contaminants. Housing and community based interventions in low income communities are likely to contribute to reducing health disparities in the US.

We will also work with Tribes, states and local communities to design and implement policies that improve the environment and protect children. We will work to ensure safe and healthy places for children to live, learn, work and play by providing leadership and focus to America's community infrastructure, its homes, schools, child care centers, farmlands and workplaces.

As part of our efforts in all these areas, we will utilize our Children's Health Protection Advisory Committee to help ensure that we are developing effective strategies to address the most significant threats to children's environmental health.

Conclusion

Thank you, Chairman Boxer, and members of the Committee for the opportunity to talk to you today. As evident by our strategy and actions, Administrator Jackson and I share your commitment to children's environmental health and we appreciate your ongoing interest in our efforts. Thank you again for inviting me to give testimony and I look forward to answering any questions you might have.

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[1] America's Children and the Environment. U.S. Environmental Protection Agency. http://www.epa.gov/envirohealth/children/index.htm

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[8] Centers for Disease Control and Prevention, National Center for Health Statistics, National Health Interview Survey. http://www.cdc.gov/nchs/nhis.htm

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[16] Akinbami LJ. The State of childhood asthma, United States, from 1980 to 2005. Advance data from vital and health statistics; no 381, Hyattsville, MD: National Center for Health Statistics.

[17] Ibid.

[18] http://www.epa.gov/asthma

[19] http://www.epa.gov/asthma/ahop.html

[20] http://www.asthmacommunitynetwork.org

[21] SOURCE: America's Children and the Environment. U.S. Environmental Protection Agency. http://www.epa.gov/envirohealth/children/index.htm. DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey, http://www.cdc.gov/nchs/nhanes.htm

[22] "Elevated Blood Lead Levels" is defined as a blood lead level great than 10 μ*g/dL*. In 2003-2006, Black children had the highest median blood lead level of 2.3 μg/dL, compared with 1.4 μg/dL for White children and 1.5 for Mexican-American children. SOURCE: America's Children and the Environment. U.S. Environmental Protection Agency. http://www.epa.gov/envirohealth/children/index.htm. DATA: Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey, http://www.cdc.gov/nchs/nhanes.htm. The disparity is important to note as research continues to show adverse effects at lower and lower blood lead levels. For more information about health effects at lower blood lead levels, see the National Ambient Air Quality Standards for Lead Final Rule, 73 FR 66964.

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Environment and Public Works Committee Hearing
March 17, 2010
Follow-Up Questions for Written Submission for Grevatt

Senator Barbara Boxer

1. The Committee has received testimony from a scientist on the second panel, Dr. Gina Solomon, which describes scientific risk assessments principles used in the State of California to safeguard children's health.

Would you commit the Office of Children's Health Protection to meet with my staff and children's health experts to discuss how EPA can adopt such protections if they provide stronger safeguards for children's health than the Agency currently provides?

Will you then provide a written report to my staff on how you would adopt such protections?

EPA's efforts to implement the nation's environmental laws must use the best science to include a focus on children. I welcome the opportunity to meet with your staff and children's health experts to discuss the scientific risk assessment principles used in the State of California to safeguard children's health, and we will of course keep your staff informed as we address these risk policy issues within the Agency.

2. Two recent reports by the National Academy of Sciences recommend specific ways to update the risk assessment process to better protect children's health.

Would you commit the Office of Children's Health Protection to meet with my staff and children's health experts to discuss how EPA can adopt these recommendations if they provide stronger protection for children's health than the Agency currently provides?

Will you then provide a written report to my staff on how EPA would adopt these recommendations?

I welcome the opportunity to meet with your staff and children's health experts to discuss the specific ways to update the risk assessment process to better protect children's health recommended in the National Academy of Sciences' two recent reports. As with the discussion on the California risk assessment principles, we will be glad to keep your staff informed as we address these important risk assessment process issues within the Agency.

3. The GAO recommended that EPA update its National Agenda to Protect Children's Health from Environmental Threats, which EPA issued in 1996. GAO said that this Agenda gave the Office of Children's Health Protection leadership and credibility across EPA for addressing children's health protections.

Dr. Grevatt, do you agree to produce a National Agenda to help target and address current and emerging threats to children's health?

The 1996 National Agenda was an important milestone in establishing the Office of Children's Health Protection at EPA and clearly communicating the Agency's commitment to protecting children's environmental health. The Administrator reaffirmed this commitment in her February 4, 2010 memo, "EPA's Leadership in Children's Environmental Health," which is attached (Attachment 1). Since the publication of the National Agenda, EPA and the Office of Children's Health Protection have made significant progress in protecting children's environmental health. EPA's Office of Children's Health Protection is in the process of developing a strategy for Children's Environmental Health, and we are working with programs across the Agency to incorporate children's health into the National Program Manager's guidance documents and the Agency's Strategic Plan. We will be glad to keep your staff informed as we address these important risk assessment process issues within the Agency.

4. The GAO report found that EPA in 2008 stopped tracking whether rulemakings involved disproportionate environmental or safety risks for children. GAO said that system helped ensure accountability in EPA's actions.

The Agency agreed with GAO's recommendation to strengthen its data system, and your testimony states EPA now requires information on whether a rule will likely have an adverse impact on children's heath and the nature of the impact. Thank you for making this change.

Can you please describe how EPA will use this information to help the Agency assess the effectiveness of its safeguards?

The Agency will use this information to help identify and track actions related to protection of human health and to help ensure that these actions are based on information and assessments that appropriately account for children's unique vulnerabilities. In addition, the Office of Children's Health Protection is working with programs and Regions during the action development process to ensure children's unique vulnerabilities are appropriately accounted for.

5. In 1995, the EPA created an agency-wide policy to ensure that it consistently and explicitly evaluated health risks to infants and children in agency risk assessments and other similar documents. GAO found the agency has not consistently applied this policy.

Will you commit to have the Office of Children's Health Protection conduct a review of Agency risk assessments, risk characterizations, policies and other similar documents to help ensure that EPA is complying with the 1995 Policy?

The Office of Children's Health Protection is now actively working with programs and Regions across the Agency to ensure that risk assessments, risk characterizations, policies and other similar documents are consistent with the provisions of the 1995 policy.

6. The GAO found that EPA's strategic planning process, which guides the agency in how to carry out its mission to protect public health, has repeatedly failed to include children's health as a specific goal.

I believe that protecting children from environmental threats should be an explicit goal that helps to guide the agency actions and ensure accountability.

Do you commit to work within EPA to make express children-specific goals, objectives and targets a part of the Agency's forthcoming strategic plan for 2009 to 2013?

The Office of Children's Health Protection is actively engaged in the development of the Agency's Strategic Plan to ensure the final plan appropriately reflects the Administrator's priority for children's environmental health.

7. The GAO found that the effectiveness of the Office of Children's Health Protection has declined without consistent leadership, and without direct and meaningful support from the agency administrator.

Dr. Grevatt, do you agree to re-evaluate the mission of the Office of Children's Health Protection to make it an agency-wide champion for protecting children's health?

If so, please describe the specific actions EPA intends to take to achieve these goals.

In her memo, reaffirming that protecting children's health is central to EPA's work (February 4, 2010; Attachment 1), the Administrator identified the Office of Children's Health Protection as having the lead in ensuring that EPA programs and Regions are successful in their efforts to protect children's health and described the following three key areas in EPA's agenda to ensure that the Agency's actions address the environmental origins of health problems in children:

First, our efforts to implement the nation's environmental laws must use the best science to include a focus on children. EPA will robustly and transparently address the potential for and uniqueness of health effects in children during the development of regulations and Agency policies with human-health implications. EPA will work with states and tribes to ensure that regulations are effectively implemented and enforced to protect children's health. We will also work closely with external research partners to fill critical data gaps on children's health.

Second, we will protect children through safe chemicals management. Safe chemicals management is one of the top priorities for EPA's future largely because of the disproportionate effects of chemical exposures on children. EPA will establish standards, policies and guidance at home and abroad that help eliminate harmful prenatal and childhood exposures to pesticides and other toxic chemicals. We will work with Congress and stakeholders to identify effective approaches for the protection of children's health in the context of TSCA reform. We will also encourage green chemistry and safer alternatives to chemicals and products that present a potential hazard to children.

Third, EPA will coordinate national and international community-based programs to eliminate threats to children's health and measure and communicate progress. We will expand implementation of successful community-based programs to protect and improve children's health outcomes. That effort will focus on underserved communities, including tribes and other areas where children's health is at heightened risk. The Office of Children's Health Protection will work with program offices and regions to develop and track indicators of progress in protecting children's health, and we will communicate that progress to the public.

8. The GAO's report describes understaffing of and limited resources for EPA's children's health coordinators at regional offices, which help to strengthen safeguards for children's health.

Do you commit to work within EPA to establish key children's environmental health staff in each program and regional office to ensure proactive cross-agency implementation of priorities and goals?

If so, could you please describe the specific steps you intend to take and a timetable for achieving those steps?

Coordination and collaboration across the Agency is a pivotal part of the work of the Office of Children's Health Protection. I am working with leadership in each program and regional office to ensure that EPA actions are protective of children's health and to identify opportunities to integrate children's health protection into the Agency's routine activities. I am also working with senior leadership across EPA's programs and regions to ensure the children's health focus is appropriately reflected in the National Program Manager's guidance documents and in the Agency's Strategic Plan.

9. Dr. Grevatt, the GAO found that EPA has failed to proactively use the Children's Health Protection Advisory Committee to maintain a focus on protecting children's environmental health. The Committee contains representatives from industry, researchers, health care providers, academics, children's health advocates, and government.

Do you commit to work within EPA to help ensure that other offices and programs proactively use the Children's Health Protection Advisory Committee to provide advice on regulations, guidance, programs, plans, and policies?

If so, please describe the steps that you will take to ensure this coordination, and a timeline for implementing such actions.

The Children's Health Protection Advisory Committee (CHPAC) is a critical resource for providing independent, expert advice to the Administrator on priority Agency actions impacting children's environmental health. The CHPAC recently provided advice in a letter to the Administrator on EPA's efforts to develop school siting guidelines (Attachment 2), engaged on the school air toxics monitoring effort and is providing advice on the development of key indicators of children's environmental health. Going forward, the Office of Children's Health Protection will work with each program and regional office to proactively use the CHPAC to provide advice on Agency actions and policies.

The CHPAC meets 2-3 times each year. In advance of each meeting the Director of the Office of Children's Health Protection will engage with senior management across the Agency to identify actions, programs and issues on which to engage the CHPAC and to track the progress of implementation of CHPAC recommendations.

Additionally, the Office of Children's Health Protection will coordinate with other EPA Federal Advisory Committees to identify issues with overlapping interests so that advice from these committees can more fully address issues related to children's environmental health.

10. The EPA's Children's Health Protection Advisory Committee provides recommendations to the agency on protecting children's health. In 2007, the committee wrote a letter to EPA detailing seven recommendations that the agency could undertake to renew EPA's vision on children's environmental health.

Is the Office of Children's Health Protection working to ensure that the Agency implements these seven recommendations?

If so, please describe the specific steps that the office is taking or plans to take to help ensure these recommendations are implemented, including whether the office will check back in with the committee to gauge the pace and quality of such implementation?

Please also provide a timetable for taking each such action.

If not, do you commit to work within EPA to implement the Children's Health Protection Advisory Committee's recommendations?

The issues identified in the seven recommendations from the CHPAC are important topics that we are incorporating in our work to achieve the goals outlined in the Administrators memo, "EPA's Leadership in Children's Environmental Health" (Attachment 1). The seven recommendations are

1) **Ensure healthy environments where our children live, learn and play;**
   In her February 4 memo to the Agency, Administrator Jackson reaffirmed EPA's policy to consider the health of pregnant women, infants and children consistently and explicitly in all activities the Agency undertakes related to human health protection, both domestically and internationally, and identifies the Office of Children's Health Protection as the overall

lead for this effort. We are currently working with EPA's program offices and Regions to ensure that these priorities are carried out. For example, OCHP staff: participate in regulatory development workgroups for children's health related Agency actions under development such as National Ambient Air Quality Standards; coordinate with the Office of Chemical Safety and Pollution Prevention on chemical action plans; and engage with outreach programs across the agency, such as Tools for Schools and Indoor Air Plus, which focus on working with external stakeholders to address environmental health hazards where children live, learn and play.

2) **Eliminate environmental health disparities**;
   Expanding the conversation on environmentalism and working for environmental justice is one of the 7 priorities for EPA's future identified by Administrator Jackson.[1] The protection of children is a top priority in this work. OCHP is working with EPA's programs and Regions across the Agency to advance this mission. In addition, EPA is working with federal partners to re-establish the President's Task Force on Environmental Health Risks and Safety Risks to Children to enhance collaboration across the federal government to address environmental health disparities in children.
3) **Expand critical research to address environmental impacts on children**;
   OCHP is collaborating with EPA's Office of Research and Development and HHS's National Institute of Environmental Health Sciences to leverage the work of the Children's Environmental Health Research Centers to address environmental impacts in children. Additional Research Centers were added in 2010, and OCHP will work closely with the centers to help ensure that the expanded research activities address critical gaps on environmental impacts on children.
4) **Strengthen the national approach to regulating chemicals and providing safe alternatives**;
   Administrator Jackson identified ensuring safe chemicals management as one of the 7 priorities for EPA's future in part because of disproportionate impacts of chemical exposures on children. OCHP is working with the Office of Chemical Safety and Pollution Prevention on efforts to reduce harmful pesticide exposures to agricultural workers and their families. Additionally, OCHP is working with the Office of International and Tribal Affairs on international programs which help eliminate harmful prenatal and childhood exposures to pesticides and other toxic chemicals.
5) **Foster environmental preparedness and prevention for children's health**;
   Since 2007, OCHP has been working with EPA's Office of Homeland Security and EPA's Office of Emergency Management to ensure that children's unique vulnerabilities are addressed in the context of environmental preparedness and prevention. OCHP included environmental preparedness and prevention on the agenda for the March 2010 meeting of the Children's Health Protection Advisory Committee. This meeting included a presentation from the National Commission on Children and Disasters.
6) **Institute "environmental health literacy" across America**; and
   In 2009, OCHP increased our funding for the network of Pediatric Environmental Health Specialty Units (PEHSUs) that we co-sponsor with HHS. The primary focus of the PEHSUs is to expand environmental health literacy within both the health care provider community and with the public at large to help ensure protection of children's environmental health. In addition, we will continue to work with EPA's programs and

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[1] See: http://blog.epa.gov/administrator/2010/01/12/seven-priorities-for-epas-future/

Regions to ensure that Agency activities related to children's environmental health include a focus on public outreach and education to enhance environmental health literacy.

7) **Commit the necessary EPA infrastructure, and inter-agency collaboration to implement the renewed vision**
The resources for OCHP were increased in FY 2010, consistent with the Administrator's priority for children's environmental health. The President's budget request for FY 2011 includes a further increase in OCHP's budget for the Clean Green and Health Schools Initiative. In addition, EPA is addressing this recommendation through the activities of the CHPAC as well as in or collaboration with federal partners on the reinvigoration of the President's Task Force on Environmental Health Risks and Safety Risks to Children.

Senator David Vitter

1. Please discuss some of the agency priorities and strategies you are hoping to implement over the next three years to better protect children's health?

EPA's children's health protection efforts are guided by Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks), its Policy on Evaluating Health Risks to Children (1995), the Guide to Considering Children's Health When Developing Agency Actions, various statutory requirements, and the best available research and data on children's health risks.

As discussed in the Administrator's February 4, 2010 memo reaffirming EPA's commitment to protecting children's health (Attachment 1), below are three key areas in EPA's agenda to both focus and ensure that the Agency's actions address the environmental origins of health problems in children and are protective of children's environmental health:

First, our efforts to implement the nation's environmental laws must use the best science to include a focus on children, EPA will robustly and transparently address the potential for and uniqueness of health effects in children during the development of regulations and Agency policies with human-health implications. EPA will work with states and tribes to ensure that regulations are effectively implemented and enforced to protect children's health. We will also work closely with external research partners to fill critical data gaps on children's health.

Second, we will protect children through safe chemicals management. Safe chemicals management is one of the top priorities for EPA's future largely because of the disproportionate effects of chemical expossures on children. EPA will establish standards, policies and guidance at home and abroad that help eliminate harmful prenatal and childhood exposures to pesticides and other toxic chemicals. We will work with Congress and stakeholders to identify effective approaches for the protection of children's health in the context of TSCA reform. We will also encourage green chemistry and safer alternatives to chemicals and products that present a potential hazard to children.

Third, EPA will coordinate national and international community-based programs to eliminate threats to children's health and measure and communicate progress. We will expand implementation of successful community-based programs to protect and improve children's health outcomes. That effort will focus on underserved communities, including tribes and other areas where children's health is at heightened risk. The Office of Children's Health Protection will work with program offices and regions to develop and track indicators of progress in protecting children's health, and we will communicate that progress to the public.

2. When do you foresee the EPA updating the National Agenda for Children's Health?

The 1996 National Agenda was an important milestone in establishing the Office of Children's Health Protection at EPA and clearly communicating the Agency's commitment to protecting children's environmental health. The Administrator reaffirmed this commitment in her February 4, 2010 memo, "EPA's Leadership in Children's Environmental Health," which is attached (Attachment 1). Since the publication of the National Agenda, EPA and the Office of Children's Health Protection have made significant progress in protecting children's environmental health. EPA's Office of Children's Health Protection is in the process of developing a strategy for Children's Environmental Health, and we are working with programs across the Agency to incorporate children's health into the National Program Manager's guidance documents and the Agency's Strategic Plan. We will be glad to keep your staff informed as we address these important risk assessment process issues within the Agency.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FEB 4 2010

THE ADMINISTRATOR

MEMORANDUM

SUBJECT: EPA's Leadership in Children's Environmental Health

FROM: Lisa P. Jackson
Administrator

TO: Assistant Administrators
Associate Administrators
General Counsel
Regional Administrators

Protecting children's environmental health is central to our work at EPA. As we move ahead on critical environmental initiatives and sharpen our focus on our seven priorities for EPA's future, we must ensure that children's health protection is a driving force in our decisions.

Let me reaffirm that it is EPA's policy to consider the health of pregnant women, infants and children consistently and explicitly in all activities we undertake related to human-health protection, both domestically and internationally. This includes consistently following Agency policies to account for specific exposure pathways and dose-response characteristics of children in our risk assessments and standard setting practices.

Research has demonstrated that prenatal and early-life exposures to environmental contaminants can have tragic, life-long effects. Children's neurological, immunological, digestive, and other bodily systems are still developing; children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; and children's behavior patterns can make them more susceptible to environmental exposures. We must be diligent in our efforts to ensure that dangerous exposures and health risks to children are prevented.

EPA will use a variety of approaches to protect children from environmental health hazards. Those approaches will include regulation, implementation of community-based programs, research, and outreach. At the same time, we must periodically evaluate our performance to ensure that we are making steady progress.

The Office of Children's Health Protection in the Administrator's Office will take the lead in ensuring that the programs and Regions are successful in their efforts to protect children's health. Please contact Office Director, Peter Grevatt if you need assistance in your efforts to make children's environmental health a priority in all Agency programs and actions.

EPA's Children's Health Agenda

EPA's children's health-protection efforts are guided by Executive Order 13045 (Protection of Children from Environmental Health Risks and Safety Risks), its Policy on Evaluating Health Risks to Children (1995), the *Guide to Considering Children's Health When Developing Agency Actions*, various statutory requirements, and the best available research and data on children's health risks.

Following are three key areas in EPA's agenda to both focus and ensure that the Agency's actions address the environmental origins of health problems in children and are protective of children's environmental health:

First, our efforts to implement the nation's environmental laws must use the best science to include a focus on children. We will robustly and transparently address the potential for and uniqueness of health effects in children during the development of regulations and Agency policies with human-health implications. We will work with states and tribes to ensure that regulations are effectively implemented and enforced to protect children's health. We will also work closely with external research partners to fill critical data gaps on children's.

Second, we will protect children through safe chemicals management. I named chemical management as one of our top priorities for EPA's future largely because of the disproportionate effects of chemical exposures on children. We will establish standards, policies and guidance at home and abroad that help eliminate harmful prenatal and childhood exposures to pesticides and other toxic chemicals. We will work with Congress and stakeholders to identify effective approaches for the protection of children's health in the context of TSCA reform. We will also encourage green chemistry and safer alternatives to chemicals and products that present a potential hazard to children.

Third, we will coordinate national and international community-based programs to eliminate threats to children's health and measure and communicate progress. We will expand implementation of successful community-based programs to protect and improve children's health outcomes. That effort will focus on underserved communities, including tribes and other areas where children's health is at heightened risk. The Office of Children's Health Protection will work with program offices and regions to develop and track indicators of progress in protecting children's health, and we will communicate that progress to the public.

I look forward to working with you to ensure that children's health is paramount at EPA.

cc: Bob Perciasepe
Diane Thompson
Bob Sussman
Ray Spears
Lisa Garcia
Larry Elworth
Peter Grevatt

Children's Health Protection Advisory Committee

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Anne Turner-Henson, R.N., D.S.N.
Nsedu Obot Witherspoon, MPH

April 7, 2010

Lisa P. Jackson, Administrator
United States Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

RE: EPA School Siting Guidelines

Dear Administrator Jackson:

In 2009 the Environmental Protection Agency (EPA) Office of Children's Health Protection requested that the Children's Health Protection Advisory Committee (CHPAC) provide assistance to EPA in fulfilling its Congressional mandate[1] to issue voluntary model guidelines for the siting of school facilities. CHPAC appreciates the request and opportunity to be involved early in EPA's response to this mandate. Ensuring healthy school environments is a major environmental public health priority as children are more susceptible to certain environmental hazards than are adults, and children spend a large portion of their childhood in schools. Childhood asthma, obesity, learning and behavior issues are all major public health concerns that can be positively or negatively affected by school siting.

The Office of Children's Health Protection established a CHPAC School Siting Task Group (SSTG) for the purpose of providing advice to EPA concerning the school siting draft guidelines. SSTG members included five CHPAC members and seventeen individuals recruited by EPA. CHPAC is pleased that EPA engaged stakeholders who represent a wide diversity of experience with issues concerning school siting.

The SSTG was charged with making recommendations on the contents and scope of a draft EPA school siting guideline document that would subsequently be available for public comment. EPA's purpose in asking for assistance from CHPAC was to ensure that comments on the draft reflected a diverse range of perspectives concerning the complex issues around school site selection and children's health. After research and deliberation the SSTG prepared an extensive report (enclosed) that contains responses to charge questions that EPA addressed to the SSTG, comments on the draft EPA guidelines, and extensive comments on school siting.

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[1] The Energy Independence and Security Act of 2007 (Federal Public Law 110-140), Section 502 of Subtitle E – Healthy High Performance Schools, requires EPA to issue national voluntary model guidelines for school siting.

CHPAC emphasizes that while these guidelines are focused on siting new schools, there are over 132,000[2] existing schools in the United States. Consequently it is critical that EPA attend to decisions that affect environmental conditions around these existing schools, especially in the country's most disadvantaged and vulnerable communities.

CHPAC urges EPA to support approaches to school siting decisions that lead to health benefits to both the school population and larger community. This principle and the others that follow are reflected in the comments and suggestions in the report. CHPAC recommends that EPA incorporate these principles into its guidance.

- Protect the health and well being of school children and school staff;
- Incorporate best practices for promoting collaborative, inclusive, and transparent site selection processes;
- Emphasize meaningful public involvement and stakeholder participation throughout the school siting process;
- Explicitly consider how the built environment supports health and healthy behaviors (e.g., increased physical activity, reduced driving);
- Incorporate an effective and rigorous environmental review process as specified in the report; and
- Promote siting on uncontaminated sites.

CHPAC recommends EPA incorporate the SSTG's specific comments (found in the enclosed report) into the next draft of the guidelines. In addition to the wide range of technical issues presented in the report, CHPAC members urge EPA to develop siting guidance that will result in reduced exposures to traffic related emissions. This is an emerging area of research that deserves attention beyond what is included in the report.

CHPAC urges EPA to view the issuing of guidelines as only the first step in ensuring that schools have proper support for making sound siting decisions. Mindful of the diversity of resources among local, state and tribal governments, CHPAC strongly recommends that the EPA provide these entities with individualized leadership, actionable strategies, and technical assistance in implementing EPA guidelines on school siting.

CHPAC recommends the following specific roles and tasks for EPA to undertake in order to assure guidelines are used effectively:

- Provide regional and national EPA technical support for school siting activities.
    - Establish and fund/support EPA staff at the regional level to provide technical support for environmental review.
    - Evaluate the extent to which states have the necessary capacities and authorities to integrate the guidelines into their siting decision processes.
    - Include resources to support implementation of the guidelines (such as community access to technical assistance, grant programs for contamination assessments and remediation).
    - Evaluate the extent to which EPA can provide state and local support in developing effective public environmental communication strategies and civic

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[2] National Center for Education Statistics, 2008. Table 5: Number of educational institutions, by level and control of institution: Selected years, 1980-81 through 2006-7. Accessed March 25, 2010 http://nces.ed.gov/programs/digest/d08/tables/dt08_005.asp?referrer=list.

    training programs to specifically promote and maintain collaboration among key stakeholders in the site selection process.
    - Evaluate the extent to which EPA can assist states in developing a publicly available database of past school siting assessments to assist with future siting assessments.
    - Assist and support efforts to determine the long term cost effectiveness of considering the risks to children's health in school siting decisions.
    - Determine priorities in implementing remediation strategies.
    - Evaluate the implementation of guidelines.
    - Develop and use mechanisms to measure the impact of the school siting guidelines with particular attention to their role in addressing existing environmental disparities.
- Develop additional guidelines in related areas including construction materials and operations/maintenance procedures used in new and existing schools.
- Extend the school siting guidelines to additional learning environments, such as child care centers, preschools, Head Start and Early Head Start programs, after-school care sites, and charter and private schools.
- Establish effective coordination with multiple federal agencies.
    - Implement a federal interagency environmental health collaboration to address the school environment, siting new schools, and siting hazards in the vicinity of existing schools.
    - Evaluate the extent to which existing federal programs across all relevant agencies and authorizations can be used to promote compliance with guidelines.
    - Promote the adoption and integration of the guidelines into EPA and other agencies' policies, guidelines, and practices related to schools. For example situations where EPA or the states have authority for siting new facilities and infrastructure (e.g., roads, facilities) within screening perimeters of existing schools.

CHPAC recommends that, whenever possible, contaminated sites should be avoided, but recognizes that some local education authorities may need to consider sites that require remediation of past contamination. CHPAC recommends that EPA develop soil, air, and groundwater remediation standards that rigorously protect children's health and are specific to the unique exposures at existing and proposed school sites. Until national standards are established, CHPAC recommends consulting the best available state and local sources for such standards.

The SSTG emphasized the importance of the timing and frequency of public participation. Implementing an open and participatory siting process requires time and talents that may not be factored into an environmental review. CHPAC recommends incorporating information (as detailed in the report) and examples on the role of meaningful public participation in successful school siting into the guidelines in order to encourage state/tribal and local education authorities to devote time, staff, and funding to this important process.

CHPAC acknowledges that the guidelines may require additional resources within local education authorities in states and tribes that do not currently require or carry out rigorous environmental review on prospective school sites. However, poor school siting decisions may prove much more expensive in the long run. EPA should consider grant programs to help local municipalities defray the costs associated with the proposed siting guidelines.

CHPAC recommends that EPA provide guidelines based on best practices as a goal and model. In addition, CHPAC recommends that EPA develop information for states and tribes both on the benefits of a thorough environmental review and those steps that are most critical for ensuring that the health of the community is protected and promoted. These guidelines hold tremendous potential for reducing morbidities including childhood asthma obesity, and learning deficits and result in major cost savings in health care.

Thank you for your continued recognition that schools are an important component of assuring healthy children and healthy communities. CHPAC requests a visit from you or your representative to describe how EPA is responding to the recommendations detailed in this letter and attached report, and EPA's response to the larger issue of creating health protective school environments.

Sincerely,

Pamela Shubat

Pamela Shubat, Ph.D.
Chair
Children's Health Protection Advisory Committee

Enclosure: Report of the School Siting Task Group: Comments on US Environmental Protection Agency Draft Guidelines for the Siting of School Facilities

cc:

Peter Grevatt, Director, Office of Children's Health Protection and Environmental Education
Bob Perciasepe, Deputy Administrator
Scott Fulton, General Counsel
Gina McCarthy, Assistant Administrator for Air and Radiation
Mathy Stanislaus, Assistant Administrator for Solid Waste and Emergency Response
Steve Owens, Assistant Administrator for Prevention, Pesticides, and Toxic Substances
Paul Anastas, Assistant Administrator for Research and Development
Cynthia Giles, Assistant Administrator for Enforcement and Compliance Assurance
Peter Silva, Assistant Administrator for Water
Lisa Heinzerling, Associate Administrator, Office of Policy, Economics, and Innovation
Bob Axelrad, Office of Air and Radiation
Ann Carroll, Office of Solid Waste and Emergency Response
Henry Falk, Acting Director, National Center for Environmental Health and ATSDR, Centers for Disease Control
Kevin Jennings, Assistant Deputy Secretary, Office of Safe and Drug-Free Schools, U.S. Department of Education
Donald Yu, Senior Counselor, Office of the General Counsel, U.S. Department of Education

Senator KLOBUCHAR. Thank you, Dr. Grevatt.

Mr. Stephenson.

STATEMENT OF JOHN B. STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. STEPHENSON. Thank you, Madam Chairman.

I am pleased to be here today to discuss EPA's and the Federal Government's progress over the last 10-plus years in addressing children's environmental health issues. My testimony summarizes our full report to the Committee on these issues being released today.

The scientific evidence about children's exposure to dangerous chemicals and the health effects of these chemicals continues to mount. For example 66 percent of children live in counties that exceed allowable levels of at least one of the principal air pollutants that cause aggravated asthma—a significant problem for children, one that costs $3.2 billion in medical costs annually.

EPA and the Federal Government took several bold steps in the late 1990s to make children's environmental health a priority. In 1996 EPA issued a National Agenda to protect children's health from environmental threats. In April 1997 the President signed Executive Order 13045 that mandated a concerted Federal effort to address children's environmental health and safety risks and established an Interagency Task Force to recommend strategies to the President for protecting children.

Also in 1997 EPA created the Office of Children's Health Protection and formed the Children's Health Protection Advisory Committee. However, this early momentum waned through the last decade. Our report, while acknowledging some successes such as the increased margins of safety for pesticides and the creation of the National Children's Study, concludes that EPA's past efforts to institutionalize children's health through its National Agenda and Strategic Plan have not been sustained.

But EPA has not effectively engaged its Office of Children's Health or proactively used its Children's Health Advisory Committee, and the agency's Interagency Task Force, which is largely responsible for the Federal Government's early momentum on children's health issues, was allowed to expire in 2005.

We are encouraged that Administrator Jackson is attempting to refocus attention on children's environmental health issues and believe that the strategy just discussed by Dr. Grevatt is a step in the right direction. However, we believe that to ensure progress EPA needs to implement changes in concrete and actionable ways to institutionalize its approach to children's environmental health issues.

To this end our report makes specific recommendations to EPA to include: No. 1, updating and reissuing a National Agenda to articulate current environmental health priorities and emerging issues; No. 2, identifying and tracking rulemaking and other actions to ensure that children's health issues are fully considered; No. 3, ensuring that each new Strategic Plan expressly articulates children specific goals, objectives and targets; No. 4, reevaluating the mission of the Office of Children's Health and ensuring that it has the resources and organizational placement to carry out its mission; and No. 5, more proactively using the Children's Health Protection Advisory Committee.

We are pleased that EPA agreed with our recommendations but believe they must be successfully implemented if EPA is to incorporate protection of children's health as an integral part of its everyday business.

Finally, Madam Chairman, notwithstanding the actions that EPA can take on its own, leadership from outside the agency and across the Government will also be needed to protect children from current and emerging environmental threats.

The President's Task Force on Children's Environmental Health that expired in 2005 was comprised of nine cabinet officials and seven White House office directors and was co-chaired by the Administrator of EPA and the Secretary of Health and Human Services. We believe that this task force provided the high level infrastructure needed to coordinate Federal research and strategies for addressing children's environmental health concerns through nationwide initiatives like the National Children's Study, a study that is examining the role of environmental factors on health and diseases in children from pre-birth to age 21.

The Task Force documented this and other accomplishments and reported to the President, and in our review significantly enhanced the Nation's ability to understand, analyze and respond to environmental health risks to children. Nearly every children's health expert we talked to told us that the Task Force could help the Federal Government respond to national health and safety concerns such as recalls of toys and other children's products.

Our report recommends that the Task Force be reestablished. We are pleased that you are introducing legislation to do so, and we see this as a critical step for the Government to regain its momentum in comprehensively addressing children's health issues.

That concludes a summary of my statement, and I, too, will be happy to answer questions.

[The prepared statement of Mr. Stephenson follows:]

United States Government Accountability Office

GAO

Testimony
Before the Committee on Environment
and Public Works, U.S. Senate

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ENVIRONMENTAL HEALTH

Opportunities for Greater Focus, Direction, and Top-Level Commitment to Children's Health at EPA

Statement of John B. Stephenson, Director
Natural Resources and Development

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GAO-10-545T

Madam Chairman and Members of the Committee:

I am pleased to be here today to discuss highlights of GAO's report about the Environmental Protection Agency's (EPA) efforts to institutionalize the protection of children's health. EPA's mission is to protect human health and the environment. As a result of mounting evidence about the special vulnerabilities of the developing fetus and child, the federal government and EPA took several bold steps to make children's environmental health a priority in the late 1990s. In 1996, EPA issued the *National Agenda to Protect Children's Health from Environmental Threats* (National Agenda) and expanded the agency's activities to specifically address risks for children, documenting EPA's plans to achieve seven goals, such as (1) ensuring that all standards set by EPA are protective of any heightened risks faced by children; (2) developing new, comprehensive policies to address cumulative and simultaneous exposures faced by children; and (3) expanding community right-to-know to allow families to make informed choices concerning environmental exposures to their children.

In April 1997, the President signed Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks (Executive Order), which mandated a concerted federal effort to address children's environmental health and safety risks. The Executive Order established, among other things, an interagency Task Force on Environmental Health Risks and Safety Risks to Children (Task Force) and charged it with recommending strategies to the President for protecting children's health and safety. Also in 1997, EPA created the Office of Children's Health Protection (Office of Children's Health) to support the agency's efforts and formed the Children's Health Protection Advisory Committee (Advisory Committee) to provide advice, information, and recommendations to assist the agency in the development of regulations, guidance, and policies relevant to children's health.[1]

EPA's Advisory Committee has raised concerns about whether the agency has continued to maintain its earlier focus on protecting children or capitalized on opportunities to tackle some significant and emerging environmental health challenges. For example, the Advisory Committee wrote to the Administrator in April 2007 to reflect on EPA's achievements in the 10 years since the Executive Order was signed. The committee cited successes, such as increased margins of safety for pesticides mandated under the Food Quality Protection Act and the creation of the National Children's Study. However, the Advisory Committee also expressed serious concerns about EPA's continued lack of focus on children's environmental health issues and the lack of progress in addressing the committee's many recommendations. In the intervening years, children's environmental health has become no less pressing. In fact, according to EPA data, 66 percent of children live in counties that exceed allowable levels of at least one of the principle air pollutants that cause or aggravate asthma, contributing to $3.2 billion in medical costs per year, according to the Centers for Disease Control and Prevention.

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[1] In 2005, EPA expanded the office to include environmental education and aging initiatives, renaming it the Office of Children's Health Protection and Environmental Education.

In light of concerns about EPA's focus on children, you asked that we assess the agency's consideration of children's environmental health. This statement summarizes highlights from our report being released today that addresses the extent to which EPA has institutionalized the protection of children's health from environmental risks through (1) agency priorities, strategies, and rulemakings, including implementation of Executive Order 13045; (2) the use of key offices and other child-focused resources, such as the Office of Children's Health and the Advisory Committee; and (3) involvement in federal interagency efforts to protect children from current and emerging environmental threats.[2] To perform this work we, among other things, interviewed officials from multiple EPA program offices most directly involved with children's health issues; reviewed key EPA children's health-related policies, strategic and performance plans, and guidance documents; analyzed regulations subject to the regulatory requirements of the Executive Order; and identified the accomplishments of the Task Force.

In preparing this testimony, we relied on our work supporting the accompanying report. That report contains a detailed overview of our scope and methodology. All of our work for this report was performed in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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[2] GAO, *Environmental Health: High-level Strategy and Leadership Needed to Continue Progress toward Protecting Children from Environmental Threats*, GAO-10-205 (Washington, D.C.: Jan. 28, 2010).

EPA's Past Efforts to Institutionalize Children's Health Through its National Agenda and Strategic Plan Have Not Been Sustained

As detailed in our report, EPA has developed policies and guidance to consider children, but it has not maintained attention to children through agency priorities and strategies. Specifically, EPA has not institutionalized the agency's commitment to children's health through, for example, an update to its National Agenda and an emphasis on protecting children in its forthcoming strategic plan.

First, EPA has not updated the National Agenda in more than 10 years. Issued in 1996, the National Agenda established children's environmental health as a top priority and a central focus of all agency efforts. In it, EPA articulated the agency's commitment to children's health by identifying an array of environmental threats to children and specifying a multifaceted approach to accomplishing its children's health goals. The National Agenda also was the impetus for the creation of EPA's Office of Children's Health, which was formed to support the agency's implementation of the National Agenda. Moreover, the National Agenda also helped to institutionalize the agency's commitment to the issue. According to current and former officials from the Office of Children's Health, the National Agenda and Executive Order helped legitimize the office's importance across the rest of the agency. As detailed in our report, several demonstrable children's health-focused activities were initiated in the years immediately following EPA's issuance of the National Agenda. For example, in 1999 the agency explored—through the Task Force—the feasibility of a longitudinal cohort study of environmental effects on parents and children, which Congress later established as the National Children's Study.[3] In 2000, EPA issued a strategy for research on environmental risks to children that established EPA's long-term program goals and documented its rationale.[4] The National Agenda also asserted EPA's leadership across the federal government and called on partners in Congress, industry, health professions, and interest groups to adopt and help EPA implement these children's health priorities. EPA officials with whom we spoke recognized the importance of the National Agenda for helping to institutionalize children's health as a priority across EPA, noting that it gave children's health more traction and consideration in EPA programs and activities. Our report provides examples of key actions that EPA took in accordance with the National Agenda's seven priority areas. More recently, however, EPA took actions that directly contradicted National Agenda priorities, indicating that the agency lost some of its initial focus on children's environmental health. For example, as we reported in 2007, EPA finalized a rulemaking in December 2006 that significantly reduced the amount of publicly available information reported to the Toxics Release Inventory (TRI) about toxic chemicals released into air, water, and land.[5] This action undermined EPA's National Agenda priority of expanding community right-to-know, which was designed to allow families to make informed choices about their children's exposure to toxic chemicals in their communities. In 2009, Congress acted to overturn EPA's rulemakings by restoring the original TRI reporting requirements for toxic chemicals released into the environment.[6]

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[3] Children's Health Act of 2000, Pub. L. No. 106-310.

[4] The research strategy has not been updated since its publication. Instead, EPA integrated children's environmental health into Office of Research and Development multiyear human health research plans.

Our report also addresses concerns related to EPA's strategic plans. The forthcoming plan, originally scheduled for issuance in September 2009, has been delayed to allow additional time for review by the agency's new leadership. EPA identified children's health as a cross-agency program in its 1997 and 2000 strategic plans. However, EPA's 2003 and 2006 (current) plans did not include children's health as an explicit goal or program. To help develop the agency's 2009 strategic plan, EPA held meetings in 2008 and 2009 to identify target areas for improvement. In the latest draft of that plan that EPA provided to us, the agency identified target areas for improvement—significant changes in strategy or performance measurement that are critical for helping the agency achieve and measure environmental and human health outcomes. We found that children's health was not included as a target area in the draft strategic plan, and it is not yet clear to what extent children's health will be addressed in the final plan, which is subject to revision before the Administrator finalizes it in the coming months. We also found that the Office of Children's Health was not a lead office for developing the plan's Healthy Communities and Ecosystems goal, the strategic goal that includes children's health. Development of this goal has been co-led by EPA's Office of Prevention, Pesticides and Toxic Substances; Office of Research and Development;

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[5] GAO, *Toxic Chemical Releases: EPA Actions Could Reduce Environmental Information Available to Many Communities*, GAO-08-128 (Washington, D.C.: Nov. 30, 2007).

[6] Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 425 (2009).

and Office of Water. EPA planning officials told us that staff from the Office of Children's Health attended at least one development meeting for the goal. However, the office staff said their input was not given much weight, since three other offices were assigned the leadership role for coordinating the goal's team. EPA officials said that a possible reason the Office of Children's Health did not become central to the process was that it is not directly responsible for implementing or overseeing any of the EPA programs and subobjectives included under the plan's Healthy Communities and Ecosystems goal.

In Recent Years, EPA Has Not Fully Used Its Office of Children's Health and Advisory Committee

We also found that, in recent years, EPA has not fully used the Office of Children's Health Protection and its Advisory Committee, among other child-focused resources. Although EPA now has a new Director of Children's Health, EPA's Office of Children's Health experienced multiple changes in leadership over the last several years, impairing its ability to fulfill its priorities and commitments. From 2002 to 2008, the office had four acting directors and no permanent director. EPA staff told us the Office of Children's Health had difficulty maintaining focus because of the varied priorities and initiatives of each director. For example, in 2007, the acting director tasked office staff to form workgroups and collaborate with senior program office staff across the agency in response to a set of key recommendations from the Advisory Committee. In April 2007, to mark the 10th anniversary of the Executive Order, the Advisory Committee provided recommendations in seven key areas of concern, including the need for EPA to eliminate environmental health disparities among low-income and minority children, strengthen the national approach to regulating toxic chemicals, and provide necessary leadership and infrastructure to protect children's health. For example, the Advisory Committee had recommended expanding research and committing additional EPA infrastructure to children's health, among other things, and the EPA Administrator and office's acting director committed to addressing the recommendations. The office's subsequent acting director eliminated the workgroups, and EPA has yet to meaningfully address the Advisory Committee's recommendations.[7]

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[7] The Advisory Committee has previously noted leadership challenges in the office, writing in a December 2002 memo to the Administrator that the office could not continue to play a key role within EPA and across the nation without permanent leadership. In May 2004, EPA's Inspector General reported that the lack of a permanent director may have a negative impact on the longevity and importance of the children's environmental health program within EPA.

In our September 2008 testimony, we recommended that the Administrator examine ways to more proactively use the Advisory Committee to reinvigorate the agency's focus on protecting children's health.[8] Since that time, EPA's Administrator and the Director of EPA's Office of Children's Health have met with the Advisory Committee in March and July 2009, respectively. In his remarks to the Advisory Committee, the Director expressed his commitment to more proactively use the Advisory Committee to support EPA's efforts to protect children's health. Specifically, he said that EPA could more effectively use the Advisory Committee for advice in developing regulations, and he asked for input on how to engage the Advisory Committee early and often in rulemakings. He also said that the committee could provide leadership in the area of science policy at EPA and advise the agency on policies for conducting research and making decisions in instances where EPA lacks conclusive information about children's vulnerabilities. The Director also recently asked the committee to provide EPA with advice on its draft school siting guidelines, voluntary guidance that takes into account factors such as the special vulnerabilities of children to hazardous substances or pollution at a potential school site.[9]

Task Force Fulfilled a Critical Role for Strategy Development and Interagency Coordination until it Expired in 2005

The Executive Order provides EPA with opportunities for leadership and coordination across the federal government. However, key provisions of the Executive Order—specifically an interagency task force that reports to the President—were allowed to lapse in 2005. The President's Task Force on Children's Environmental Health and Safety Risks was authorized by the Executive Order in April 1997 for a period of 4 years to provide high-level leadership and interagency coordination on children's environmental health. It comprised nine cabinet officials and seven White House office directors and was co-chaired by the Administrator of EPA and the Secretary of the Department of Health and Human Services (HHS). The Task Force convened five times for meetings in October 1997, April 1998, January 1999, September 1999, and October 2001. As part of National Children's Health Month in October 2001, the President extended the Task Force for 2 years. According to EPA officials, the Administrator urged the

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[8] GAO, *Environmental Health: EPA Efforts to Address Children's Health Issues Need Greater Focus, Direction, and Top-Level Commitment,* GAO-08-1155T (Washington, D.C.: Sept. 16, 2008).

[9] EPA Siting of School Facilities, http://www.epa.gov/schools1/siting.html, accessed March 11, 2010.

President to continue the Task Force; in April 2003, the President extended it for a final 2 years. However, the final order eliminated the provision for reassessing the need for continuance of the Task Force, which was not convened after the October 2001 meeting. According to EPA officials involved on the steering committee, the agency was not able to convene the Task Force thereafter, for reasons related to new priorities following the September 11, 2001, terrorist attacks. Nonetheless, a senior career-level staff steering committee continued to meet until 2005 to coordinate and implement the strategies that the Task Force developed to address the threats to children's health.

The Task Force contributed to eight areas related to children's health, including the establishment of the National Children's Study, the largest long-term study of environmental influences on children's health and development, which was initiated as part of the Children's Health Act of 2000. The Task Force also identified four major environmental and safety threats to children—asthma, developmental disabilities (including lead poisoning), cancer, and unintentional injuries—and created national strategies for each of them. In its strategy documents, the Task Force recognized that an integrated solution was needed across the federal government to address the complex interaction between a child's biology, behavior, and the physical, chemical, biological, and social environment. The Task Force provided critical leadership on several important initiatives such as the National Children's Study and the Healthy Schools Environments Assessment Tool (HealthySEAT). These national programs focus heavily on the environmental influences on children's health, with the National Children's Study examining the role of environmental factors on health and disease and HealthySEAT offering school districts a self-assessment tool for identifying and evaluating environmental, safety, and health hazards.

With the Task Force's expiration, EPA and HHS no longer have a high-level infrastructure or mandate to coordinate federal strategies for children's environmental health and safety. According to the EPA staff and children's health experts with whom we spoke, had the Task Force continued, it could have helped the federal government respond to the health and safety concerns that prompted the 2007 recall of 45 million toys and children's products because of lead contamination. Furthermore, since the Task Force provision of the Executive Order expired in 2005, the Task Force's reports are no longer generated. Those reports collected and detailed the interagency research, data, and other information necessary to enhance the country's ability to understand, analyze, and respond to environmental health risks to children.

Since the President signed the Executive Order in 1997, every EPA Administrator has stated that children's environmental health is a priority at the agency, and Administrator Jackson is no exception. We would like to note the Administrator has made children's environmental health a signature item at EPA. In her first memo to EPA staff, the Administrator highlighted children as a key focus. Also, in her remarks at the April 2009 G8 Environmental Minister's Meeting, the Administrator stated,

> We have learned much in the last 12 years about the ways that environmental exposures uniquely affect children. With that increased knowledge, our sense of urgency for further action on children has also increased....The U.S. government, under this new administration, will keep faith with the promise we've made to future generations. I hope we can continue the work we started in 1997, renewing our commitment to protect children from environmental threats where they live, learn, work and play.

In our report being released today, we are making eight recommendations to help EPA reinvigorate its early emphasis on children, assume high-level leadership, and develop strategies for coordinating efforts addressing children's environment health both within the agency and throughout the federal government. For example, we recommend that the EPA Administrator update and reissue a child-focused strategy, such as the 1996 national agenda, to articulate current national environmental health priorities and emerging issues. We further recommend that EPA's forthcoming strategic plan expressly articulate children-specific goals, objectives, and targets. We make 6 additional recommendations to the EPA Administrator to maximize opportunities to institutionalize children's health throughout the agency. EPA responded that our report accurately portrays the agency's challenges in addressing children's environmental health and sets forth sound recommendations to better incorporate protection of children's health as an integral part of EPA's everyday business.

Because EPA alone cannot address the complexities of the nation's challenges in addressing environmental health risks for children, we encourage Congress to re-establish a governmentwide task force on children's environmental health risks, similar to the one previously established by Executive Order 13045 and co-chaired by the Administrator of EPA and the Secretary of Health and Human Services. We encourage Congress to charge it with identifying the principal environmental health threats to children and developing national strategies for addressing them. We further encourage Congress to establish in law the Executive Order's requirement for periodic reports about federal research findings and research needs regarding children's environmental health.

Madam Chairman, this concludes my prepared remarks. I would be happy to respond to any questions that you or other Members of the Committee may have.

For questions or further information regarding this statement, please contact John Stephenson, Director, Natural Resources & Environment at (202) 512-3841 or stephensonj@gao.gov. Diane Raynes, Assistant Director; Elizabeth Beardsley; Timothy Bober; Mark Braza; Emily Hanawalt; Terrance Horner, Jr.; Aaron Shiffrin; Benjamin Shouse; and Kiki Theodoropoulos made key contributions to this statement. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this testimony.

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GAO Response to Questions

Questions from Senator Barbara Boxer

1. **The GAO report states that EPA needs to "reinvigorate its leadership and focus on children's environmental health in concrete and actionable ways." I also believe that the public deserves to hear the specific steps that EPA will take to better protect children's health, and a timetable for implementing such actions. Could you please describe some of the high-priority actions that GAO expects EPA to undertake on a fast timetable, and the potential benefits to children's health from such activities?**

   In the report, we identify several specific actions to reinvigorate EPA's leadership and focus on children's environmental health in our recommendations. Leadership is of critical importance to the Office of Children's Health because it is supported by few resources and has a small number of staff, and because responsibility for implementing agencywide children's health priorities ultimately resides with EPA's program and regional offices. These conditions necessitate a proactive leader who can secure commitments from other parts of EPA to develop children-focused cross-agency activities—in short an advocate for children's health. We recommended that EPA reevaluate the mission of the office to ensure that it has the resources and organizational placement to carry out that mission.

2. **The EPA created the Office of Children's Health Protection "to make the protection of children's health a fundamental goal of public health and environmental protection in the United States." However, GAO found that EPA has not fully used the office, and GAO recommends that EPA "make the office an agencywide champion for implementation of a reissued national children's environmental health agency, policy and related goals..." How do you think EPA can most effectively give the office agencywide authority to consistently ensure implementation of such safeguards?**

   As it is currently structured, the Office sits in the Office of the Administrator, and therefore its authority comes from the Administrator. We reported that its influence has waxed and waned depending on the Administrator and Office Director at the time. The National Agenda was the Office's calling card to the program offices. Also, the Office's mission -- make protection of children's health a fundamental goal of public health in the United States -- is almost too broad and not practically measured. Simply put, how would we know we've achieved it? The Office could be charged by the Administrator with developing a new National Agenda, in collaboration with the program offices and even other federal agencies, and providing visibility of the Agenda to the public. For example, it could be released during National Children's Health Month.

3. **The GAO notes that the current Office of Children's Health Protection has "outlined a five-part approach to ensure protection of children's environmental health." What was GAO's assessment of the office's approach? Did it contain adequate details and timelines for action to clearly show how the Agency is going to better focus on protecting children's health? If not, what level of specificity does GAO believe is needed to help ensure that the Agency can be held accountable for implementing GAO's recommendations?**

   The five-part approach that Dr. Grevatt outlined is a broad, first start, as EPA stated in its response to our report. That approach identifies five priority areas, but it does not yet contain forward-looking commitments to specific research, programs, and standards that we think are necessary to hold the agency's program offices accountable for progress on the cross-cutting issue of children's health. To the best of our knowledge, the five-part approach has not been published in a way that makes an agencywide or public commitment.

4. **The EPA created the Children's Health Protection Advisory Committee to "advise EPA on regulations, research, and communication issues relevant to children." The committee includes representatives from industry, health care providers, researchers and government. GAO found that "EPA has made little use of its Children's Health Protection Advisory Committee." What benefits does GAO believe come from the committee advisory EPA on the creating of public health safeguards, research and other agency activities. What specific steps could EPA take to help ensure that the Agency increases its use of the committee?**

   The advisory committee was established to provide advice, consultation, and recommendations to EPA in the areas of research, community outreach, and the development of regulations, guidance, and policies. The committee is made up of a broad range of scientists, children's advocates, health care professionals, and representatives of industry. Shortly after the advisory committee was created, EPA charged it with identifying five standards (EPA regulations) that the agency should reconsider based on current science. In fact, the committee helped EPA review public comments on the same matter. Something similar could be done again to proactively use this advisory body.

5. **The GAO recommended that EPA establish key children's environmental health staff within each Agency program office and regional office to help ensure implementation of priority actions to protect children's health. Could you please describe why GAO made this recommendation, and some of the benefits that GAO believes will occur if EPA makes these changes?**

   Much of the work of EPA occurs in the program and regional offices, and having dedicated children's health staff in those offices would be critical to achieving goals set by a revised National Agenda. In addition, the Office of Children's Health has had detailees from EPA's program offices--Office of Water or Office of Pesticides, for example. If done in a systematic way, detailees to the Office from the major program offices may be a way to build children's health capacity at EPA.

6. **The GAO recommended that EPA update and reissue a child-focused strategy similar to EPA's 1996 National Agenda to Protect Children's Health from Environmental Threats. From GAO's perspective, what are the benefits of EPA issuing an updated National Agenda to Protect Children's Health.**

   A periodically revised National Agenda, publicly issued by the EPA Administrator, would help to organize and prioritize EPA's many children-related activities (some of which Dr. Grevatt outlined at the hearing and help hold the agency accountable for making progress. As our report and testimony showed, the agency actually reversed course from one of the seven priority areas of the 1996 National Agenda, when it rolled back the Toxics Release Inventory (TRI) reporting requirements. Some of the Agenda's goals may already be achieved, so it would also be an opportunity for EPA to take credit for progress and set new goals related to new and emerging children's health concerns such as low-level exposures to chemicals.

7. **The GAO report shows that, while EPA focused on protecting children's health in the late 1990s, with the creation of the Office of Children's Health and the development of specific children's health policies – it reduced this focus during the last decade. What are the best ways to help ensure that EPA consistently focused on protecting children's health – since years can pass between the start of an EPA initiative, to the completion of the Agency's efforts?**

   Your question relates to our recommendation regarding EPA's strategic plan. As you've written, protecting children also helps protect us all, because childhood exposures can affect health throughout the lifecourse. We would like to see more emphasis on protecting children in the agency's forthcoming 5-year strategic plan, because it helps drive the program office's annual activities. In addition, several years ago the Office had drafted its own strategic plan that was never completed or released. We have seen department/agency-level strategic plans reference such sub-plans, and EPA could do so with children's health. EPA should report, at least annually, progress in implementing the plan.

8. **In 1995, EPA issued an agencywide Policy on Evaluating Health Risks to Children, which directed EPA staff to consistently and explicitly consider risks to infants and children as part of risk assessments and when setting standards**

to protect public health and the environment. GAO recommends that EPA re-evaluate the 1995 policy to ensure its consistency with new scientific research. What type of research should EPA consider in updating its policy? How important does GAO believe this re-evaluation is for protecting children's health?

We made the recommendation because after nearly 15 years, the policy may no longer reflect current understanding of the impacts of childhood exposures on the life course. We included EPA's policy as an appendix in the report, and it states that EPA will develop a separate risk assessment, to the degree permitted by available data, for children and infants OR clearly state why this is not done. We believe that EPA needs to consider whether a separate risk assessment is necessary and the extent to which EPA's program offices are following the policy. These risk assessments form the scientific basis for regulation and therefore we believe it is very important to ensure that children are adequately considered in the assessments. Furthermore, we made a separate but related recommendation to strengthen the data system that identifies and tracks development of rulemakings and other actions to ensure they comply with the 1995 policy.

Questions from Senator David Vitter

1. **In looking at EPA's strategic plans, what do you see as the major challenges to redirecting EPA focus on children's health?**

As we identified in the report, an overarching challenge is the continued institutionalization of children's health through the various EPA program offices, where much of the science and regulatory work is carried out. As we reported, the Office of Children's Health needs a reinvigorated mission—to serve as an advocate for children's health across the agency. We also identified a diminished focus on children in EPA's recent strategic plans, relative to the first two plans following the formation of EPA's Office of Children's Health. In addition to our findings, the EPA Office of Inspector General also recently released a report that was critical of EPA's strategic planning to protect children's health. EPA agreed to implement the Inspector General's recommendation that the agency develop a strategic plan, improve annual planning, establish measures, and report its results and outcomes toward meeting EPA's National Agenda to Protect Children's Health from Environmental Threats; or devolve to other program offices the functions and resources of the Office of Children's Health.[1]

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[1] EPA Office of Inspector General, *Need Continues for a Strategic Plan to Protect Children's Health*, Report No. 10-P-0095 (Washington, D.C., Apr. 5, 2010).

2. **Do you see opportunities in EPA's current funding to redirect resources to children's health?**

   We identified the need for creating key children's health positions within each EPA program and regional office, with linkages to the Office of Children's Health, as a way to leverage current resources and better institutionalize children's health across the agency. In addition, EPA could continue to expand opportunities for program and regional staff to be detailed to the Office of Children's Health.

3. **Do you see opportunities for HHS and EPA to coordinate work and research that would be helpful in improving research and strategies in children's health?**

   We identified a significant lost opportunity for the Department of Health and Human Services and EPA to coordinate work and research when the President's Task Force expired in 2005. The task force identified the major, current environmental health threats to children, such as asthma and lead poisoning; provided consolidated reports on research activities; and developed strategies for reducing the environmental threats to children's health. EPA has identified emerging and potential threats, such as endocrine disruptors, pharmaceuticals in drinking water, and nanoscale pollution that a reinstated task force could help address.

Senator KLOBUCHAR. Thank you very much, Mr. Stephenson. Thank you for acknowledging the legislation that we are introducing. What do you see are some of the advantages of going beyond EPA and coordinating with other agencies as we want to do with this legislation?

Mr. STEPHENSON. Well, at least those 10 agencies that were on the Task Force certainly have roles in protecting children. The Consumer Product Safety Commission would be instrumental in things such as the toy recall. It could benefit from EPA's scientific assessments of chemicals that are typically used in toys. So, it just created leadership across the Government and provided great momentum for addressing this issue that has kind of waned since it expired in 2005.

Senator KLOBUCHAR. I was thinking about that when we had the latest toy issue with the cadmium in the jewelry, and how, when we had a previous hearing I asked about that, and the studies that were going on at EPA and just having that kind of coordination. It might not have been as much of a surprise as it appeared to be when suddenly there was this new problem that none of us had foreseen because we were so focused on the lead.

Mr. STEPHENSON. Yes, too, we think that the regular reports to the President on this subject help keep the public informed about what the Government is doing to protect children as well.

Senator KLOBUCHAR. I would just think that coordination might result in better legislation as you look at things, not just as a specific thing that comes to one agency, but overall.

How can we create accountability and ensure that the EPA is following through on its stated goal to make children a priority at the agency since you guys are all about accountability?

Mr. STEPHENSON. Well, as Senator Lautenberg mentioned the National Agenda that guides EPA's efforts in this area has not be updated for 10 years. I think EPA is getting there, but it is not documented yet.

We think that such a document with clear research priorities, chemical risk assessment priorities and the like are critical to guide the agency, and we think that informs the public about what EPA is doing to protect children as well. And it sends a message across the program offices and regions at EPA as well to the fact that this is an important agenda of the Administrator. We think that the regular reports that they provided to the Administrator were also instrumental in keeping the momentum going.

There are many things that we think need to be done. In the rulemaking process, we recommended better tracking mechanisms to show how children's health issues are considered in rulemaking and standard setting and other actions that EPA takes. So, there is a whole variety of things specified in our report that we think will go a long way toward institutionalizing the addressing of children's health issues at the agency.

Senator KLOBUCHAR. Thank you.

Mr. Grevatt, what will the agency do to address the findings that are in the GAO report?

Mr. GREVATT. We have already taken steps to begin addressing a number of the findings, and I appreciate very much—as we indicated in our comments to your draft report—that the recommendations are sound. And so, for example, as I mentioned in my testimony, we are already working with other Federal agencies toward the reestablishment of the Interagency Task Force on Children's Environmental Health and Safety, which we see as a critical step to helping the Nation to be able to address these key issues.

The agency has improved its tracking system for regulations to help—to better capture children's health issues, and I have significantly increased the focus of the office on rules and regulations that are being developed by the agency through my interaction with the Administrator and also with the senior career folks across the agency. I think we have an opportunity to increase the sort of reporting that you were talking about, the critical nature of that.

We have—I have requested and have received an increase in resources to my office this year and in 2010 of five full-time equivalent employees being increased in the office, and then the President's budget for 2011 includes a request for an additional 13 employees between my office and the regions to focus on healthy school environments.

Senator KLOBUCHAR. And when you talk about healthy school environments, what do you mean by that?

Mr. GREVATT. I mean to address the issues in schools that we think that can both impact children's health in those schools as well as children's academic performance in those schools. So, things like making sure the schools are dealing with moisture problems to prevent mold in the school environments to help reduce the possibility of children experiencing attacks in the school environment, making sure that when pesticides and cleaning products are used in school they are used safely so as to not inadvertently affect the children who are in those school environments, making sure there is adequate air exchange so that kids can be alert in their work and also protected from any kind of allergens other than mold that might cause asthma attacks in those school environments. So, those kinds of issues are all key to that work.

Senator KLOBUCHAR. OK, one specific question, and then I will turn it over to my colleague, Senator Udall, who has arrived.

Dr. Grevatt, in your testimony you mentioned that EPA issued the Lead Renovation Repair and Painting Rule, which aims to provide broad protections against inadvertent lead poisoning by requiring contractors and construction professionals to be trained, certified and to use lead safe work practices during renovation, repair and painting in pre-1978 housing and childcare centers.

There is broad agreement that these increased protections for children are necessary, but there is also some recent concern among consumer health organizations and people who do this type of work that there are not yet enough certified contractors to meet EPA's requirement when this rule could take effect.

I understand that EPA has less than 200 accredited trainers and less than 14,000 certified renovators nationwide. We are not quite at the 200,000 that we need to make this work. I did write a letter today to Administrator Jackson expressing concerns about implementing this rule next month, that we simply might not be ready yet, and it could not have the desired effect that we want, to reduce the lead and at the same time, because of the lack of the contractors—the trained contractors—could hinder the home energy efficiency upgrades.

Do you know what is EPA's position is on this? That was a long question.

Mr. GREVATT. It was a long question but a very important one. It is a tremendously important rule implementation; effecting implementation of that rule is tremendously important to protect children's health in home environments and other environments where they spend time. The Administrator is well aware of this issue, and I was speaking with the Deputy Administrator about it yesterday, looking toward increasing opportunities and awareness of the contractors of the need to be trained for implementation of the rule.

And I think there are a number of factors at play here. We think that we have enough trainers now to reach out to a large group of contractors across the country, but we think there is still an issue with increasing the awareness among the contracting community. It requires them to spend roughly a day in a training course with 2 hours of hands-on training, and we are not getting the response from the contractor community that we need as yet.

So, we are talking about specific ways of outreach in the near term, the very near term, to try to increase participation in the training and get those numbers up where they need to be.

Senator KLOBUCHAR. Yes, and I would suggest, just because we are working so hard with our stimulus and jobs package that, you know, perhaps some delay will be necessary with the immediate outreach and a different date because I am just concerned about these numbers so far. But that is something that I know you will be discussing at the EPA.

Mr. GREVATT. That is right. Thank you.

Senator KLOBUCHAR. OK. Thank you.

Senator Udall, I see you are wearing green. I forgot to.

Senator UDALL. Thank you, Madam Chair. I am wearing green. Somehow, I managed to remember this morning.

Senator KLOBUCHAR. You are very organized. You must be part of a coordinated green interagency task force.

Senator UDALL. No, I happened to see Senator Leahy last night in black tie on the floor, and I said, what is going on there, and they said he is going to the dinner.

Senator KLOBUCHAR. Oh, and then that made you remember. You did good. It is sort of an interagency theme. OK. There you go.

[Laugher.]

Senator UDALL. Anyway, Madam Chair, thank you very much, and thank you for focusing on this issue. I know you have a real passion for children's issues and children's health, and I look forward to really working with you on this Committee to achieve some good goals.

This question is for both Mr. Stephenson and Mr. Grevatt. The EPA's National Agenda to protect children's health from environmental threats came out in 1996. That same year Congress reauthorized the Safe Water Drinking Act with a focus on cost-benefit analysis. Since 1996 the EPA has issued few new drinking water standards.

Under the previous Administration EPA decided not to regulate perchlorate, an ingredient for explosives that harms the thyroids of pregnant women. What are the challenges of incorporating the special health effects of children in the Safe Water Drinking Act? Either one of you, jump in there.

Mr. STEPHENSON. I will defer to Dr. Grevatt on that.

Mr. GREVATT. OK. Thank you very much. A very important issue, perchlorate in particular, but more broadly, addressing contaminants in drinking water. And we are—I think you are aware that within the last year EPA reevaluated the health risks related to perchlorate and issued an updated risk assessment for perchlorate for public review. And at this point the Administrator is considering what decision to make specifically with regard to possibly regulating perchlorate as a contaminant in drinking water.

But more broadly the Safe Drinking Water Act, in addition to requiring a cost-benefit analysis, does require consideration of vulnerable populations for drinking water contaminants, including children. And we will be working very closely with the Drinking Water Office as well as other offices across the agency and their own regulatory actions to make sure that children's health vulnerabilities are considered through any rulemaking activities that will address drinking water contaminants.

Mr. STEPHENSON. The only thing I would add is that we do have some ongoing work on perchlorate right now as an emerging contaminant in drinking water, and I believe this Committee is one of the requesters for that report, which will be out later this year. It does not single out children's health issues, but it will talk about the problems that EPA has and the length of time that it takes to do chemical risk assessments in general. Perchlorate, for example, has been studied for over a decade now. And we may have some specific recommendations on the issue of chemical risk assessment coming out of that report.

Senator UDALL. Thank you.

Mr. Stephenson, you recently testified at our Committee regarding efforts to reform the Toxic Substances Control Act, which is clearly out of date, at best, and possibly fatally flawed. The question for both of you is which of the proposed reforms to this law have the most potential to provide an extra buffer zone of protection for children: biomonitoring, risk screening of chemicals, increased data for producers, or increased authority to restrict chemicals? Or does this require a comprehensive approach?

Mr. STEPHENSON. All of the above, a comprehensive approach. The biomonitoring data will tell you what chemical exists in the blood, but it does not tell you the causes or the likely health effects of that data. But biomonitoring is an important element to help prioritize which risk assessments are needed. We have not looked at all the various proposals to amend TSCA but have been studying the issue for 5 or 6 years and are definitely in support of amending TSCA and giving it more teeth and strength for the Agency and requiring more by the chemical industry in regards to proving that its chemicals are safe before they are introduced into commerce.

Mr. GREVATT. And thank you. If I may, I agree with Mr. Stephenson's comments on that. I think any one of the factors that you mentioned there would help, but without the full suite of those I think it would be very difficult for us to move forward in the way that we need to on TSCA implementation. And the Administrator,

Administrator Jackson, issued recently her key themes that she thought were important in TSCA reform, and we are very supportive of moving forward in this area.

Senator UDALL. Thank you.

There is a continuing push by business and industrial interests to include more and more cost-benefit analysis in environmental regulation. How is that effort compatible with children's environmental health, which may not be as easily quantified?

Mr. GREVATT. I am sorry, but I am not sure if that is a question for me or for both of us.

Senator UDALL. Jump in if you both want. You have, I am running out of time, so——

Mr. GREVATT. OK. Thank you very much. I think that it is important for us to focus on cost-benefit analysis related to children's environmental health, but the emphasis I would put there is doing a better job of understanding the costs associated with childhood impacts and the benefits associated with taking actions to prevent those impacts. So in particular I think there is more work that we could be doing there to better capture the benefits of steps that we take to protect kids from environmental contaminants.

Mr. STEPHENSON. I think this is a place where you can use the Children's Health Advisory Committee as well. There are several new members, including a new Chairperson, resulting in about half of the Committee being new. They are convening the new Committee later this month. EPA can ask them to use their expertise, which includes industry representation, academic representation, and special interests to address questions regarding the compatibility of cost-benefit analysis with environmental regulations related to children's health. That is why they are there. So, I think they can help EPA better determine how to consider children's health issues in that manner.

Senator UDALL. I thank both of the witness and the Chair. Thank you for your courtesy for letting me run over a little bit. I am sorry I cannot stay for the whole hearing. I think this is a very, very important subject.

Senator KLOBUCHAR. Thank you very much, Senator Udall.

One last question, Dr. Grevatt. As you know there is finally some movement afoot to do something on childhood obesity. It has been dormant. And as our recesses have gotten shorter, and our attention, I think, has gotten shorter, our kids' waistlines have gotten larger. And we just have not been devoting the attention we need to it. As you know a third of kids that now graduate from high school are obese or overweight and a fourth are obese going into elementary school.

The Child Nutrition Act, as I mentioned, is being introduced today. That is one thing. And as we go into some of the education work that will be done this summer I think we should be looking at recess and gym time as a piece of that. We have our Complete Streets Bill here where we are trying to move on community planning and things that more is done to incentivize and encourage walking. But I just wondered what EPA is doing as part of this effort.

I just see it as huge money for taxpayers. You know, we are financing—for very good reasons and necessary reasons—not just school lunches and breakfasts but also Pre-K, the Childcare Program, 3 million of these kids are getting food every day. And one of the most amazing things to me, I introduced a bill on this this week with Senator Harkin; it is now being included in the Child Nutrition Standard.

I just want to make sure you know this. They are really not just standards at all for these childcare meals. And yet we are paying for it, the taxpayers are. One out of three kids, a recent study showed that kids in these childcare programs do not even have a fruit or a vegetable all day and that the most common vegetable is french fries. And if you think about what we are giving these kids, it is just not right. And so this is something that I really believe has to be changed.

I have seen it in my daughter's own schools. The difference between being in a sort of a different demographic with parents with more money, these kids are bringing carrots and celery in their lunches, and then at the other school she was in for 3 years with 90 percent free and reduced lunch, these kids are, you know, choosing the Twinkie line and the french fries instead of the yogurt in these à la cart lines. And it seems to me the kids we are hurting most are the kids who are the most vulnerable and who need the most help during the school day. And it has to change.

So, I just wondered what EPA, what you are doing in this regard, as part of this big focus of the First Lady's, which I truly appreciate.

Mr. GREVATT. Senator, thank you very much, and I appreciate your leadership on this critical issue. And childhood obesity certainly has the potential to lead to the current generation of children being the first generation in American history who may have a shorter life expectancy than their parents. So, this is a critical issue for us to address.

As a part of the Interagency Task Force on Childhood Obesity, EPA is an active participant. All the key players are there focusing on physical activity, focusing on the built environment, focusing on food availability and food nutrition guidelines, school lunches, and a variety of other issues that intersect with obesity in some ways that may not be obvious, including the intersection between childhood asthma and childhood obesity and the intersection between some chemical factors that may lead to infant obesity.

So, EPA is an active player in this area. And I think you are aware that the President's memorandum on childhood obesity that established the Task Force gave us a 90-day timeframe to produce a report, a comprehensive report from across the Federal Government, on key steps that will be taken to address childhood obesity and eliminate childhood obesity within a generation. EPA is an active participant in that effort, and we will remain so.

Senator KLOBUCHAR. OK. Very good.

Well, thank you very much. This has been informative. I especially liked the question part. I mean, the testimony was not bad, but you know.

[Laughter.]

Senator KLOBUCHAR. I think we got some very useful information on the focus here, and I thank both of you. And now we will bring up the second panel. Thank you.

Very good. We are pleased to have the second panel here. Our first witness will be Gina Solomon, a doctor who is the Associate Director of the University of California in San Francisco Pediatric Environmental Health Specialty Unit and the Center for Occupational and Environmental Health at the University of California at Berkeley. Second, we have Cynthia Bearer, also a doctor, who is the Chief of Neonatology at the University of Maryland School of Medicine. And then, finally, we have Dr. Ted Schettler, who is the Science Director for the Science and Environmental Health Network. Thank you all for being here.

Dr. Solomon.

STATEMENT OF GINA M. SOLOMON, M.D., M.P.H., SENIOR SCIENTIST, NATURAL RESOURCES DEFENSE COUNCIL; ASSOCIATE DIRECTOR, PEDIATRIC ENVIRONMENTAL HEALTH SPECIALTY UNIT; ASSOCIATE CLINICAL PROFESSOR OF MEDICINE, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

Dr. SOLOMON. Good morning, Madam Chair and members of the Committee.

[Laughter.]

Senator KLOBUCHAR. They come and go. We have actually had very good attendance. I am excited.

Dr. SOLOMON. I think that it is a great testament to this topic, and I am very glad to be here to testify today.

I am a physician. I am also a Senior Scientist at the Natural Resources Defense Council, an Associate Clinical Professor of Medicine at UCSF, and I do work with the UCSF Pediatric Environmental Health Specialty Unit.

One of the most frequent questions that I hear from my patients is: What can I do to protect myself and my family from chemical contaminants in our air, water and food? And I always find it difficult to answer that question because most hazards to children and families are not things that individuals can really protect themselves from, even with advice from their physician. Really it is the responsibility of Government agencies such as the EPA to ensure that our air and our water are safe for pregnant women and children.

Decades of scientific evidence have accumulated demonstrating that children are more susceptible to contaminants in their environment. And in the 1990s the President and the EPA recognized that evidence and took important actions including Executive Order 13045, which we have heard about, the National Agenda to Protect Children's Health, and the creation of the Office of Children's Health Protection.

Congress recognized the overwhelming evidence on children's susceptibility when it passed child protective language in the Food Quality Protection Act. And for the first time EPA was actually required to incorporate an additional 10-fold margin of safety to protect children from pesticide residues on food and in particular was required to do that if there were data gaps.

So, this approach would seem to be a model for how to protect children. But in the last 14 years since then a couple of problems have become apparent. One of those is that the law applied only to pesticides, and to this day there are no legal requirements that

EPA actually protect children's health from other industrial chemicals including chemicals that are known to disproportionately affect fetuses and children such as bisphenol A, phthalates, brominated flame retardants, and even arsenic.

And the second problem is that EPA failed to honor even the directive of the Food Quality Protection Act. I was on an NAS committee which reported in 2006 on EPA pesticide assessments. They looked at 59 pesticides with assessments posted on EPA's Web site and EPA failed to apply the child protective factor for 48 of the 59 and only applied the full 10-fold factor to five chemicals despite the presence of widespread data gaps on many of these chemicals.

In more recent years there have been problems at EPA with their approach to protecting children from carcinogens, and that is diametrically different to the situation in California where California considers children to be more sensitive to all carcinogens unless shown otherwise. Instead EPA currently limits child protective considerations to chemicals with a mutagenic mode of action, and in their framework document sets such a high standard of proof for mutagenic mode of action that it is basically unachievable for most carcinogens, and the net result is the child protective factor is not likely to apply to the vast majority of cancer causing substances. I am encouraged to hear that EPA may revisit this policy because it clearly needs to be changed.

The biggest threat to children's health, however, in my opinion, may not be from the chemicals we already know about, the carcinogens we already know about, but from what we do not know because we are dealing with the unfortunate reality that most of the chemicals in our air and our water and even our children's toys, as you well know, have not really been tested or have not been tested at all for their toxicity.

So I am not just talking here about testing for effects on infant development but in fact for all kinds of health effects: genetic damage, neurologic damage, hormonal effects, and allergic reactions.

Basic safety assessments of all chemicals, not just pesticides, are needed in order to protect children. Only with broader chemical policy reform will parents be able to sleep soundly at night knowing that their children are safe.

Thank you very much.

[The prepared statement of Dr. Solomon follows:]

Testimony of

Gina M. Solomon, M.D., M.P.H.

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PROTECTING CHILDREN FROM ENVIRONMENTAL THREATS

Submitted in writing to
Hearing before the
Committee on Environment and Public Works
United States Senate

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Introduction

Thank you for the opportunity to submit written testimony to this Committee. I am Gina Solomon, a physician and Senior Scientist at the Natural Resources Defense Council (NRDC) and an Associate Clinical Professor of Medicine at the University of California at San Francisco (UCSF) where I am also the Associate Director of the UCSF Pediatric Environmental Health Specialty Unit. NRDC is a national, nonprofit, public interest organization dedicated to protecting human health and the environment. We have over 1.2 million members and online activists in all 50 states. I have subspecialty training and expertise in environmental medicine, and have done research, education, and advocacy for over a decade to protect children from lead poisoning, from contaminants in their food, air and drinking water, and from hazardous pesticides.

Almost every day I speak with people – both patients and members of the public – about their health and about risks to their health from environmental pollution. One of the most frequent questions I hear is: "What can I do to protect myself and my family from contaminants in the air, water, food, and in my community?" It's often difficult to answer that question. Many hazards that can affect the health of children and families are not things that individuals can protect themselves from, even with advice from their physician. Contaminants in the air we breathe, in the food we eat, or even chemicals in common household products, are things that we have little control over as individuals. It is the responsibility of government agencies such as the Environmental Protection Agency (EPA) to assure that our air and water are safe for the most vulnerable among us, including pregnant women and children.

Children are at High Risk from Environmental Contaminants

One reason that I'm concerned about children's environmental health is that some childhood diseases and abnormal conditions are on the rise. For example, childhood leukemia and brain tumors – the two most common childhood cancers – have increased by more than 20% since 1975.[1] Asthma approximately doubled in prevalence between 1980 and 1995 and has stayed at the elevated rate.[2] [3] Certain birth defects of the penis and testes, such as cryptorchidism (undescended testes), have increased 200% between 1970 and 1993.[4] And, of course, there is autism, the diagnosis of which has increased by more than 10-fold in the last 15 years.[5]

Another reason I'm concerned about children's environmental health is that decades of powerful scientific evidence has accumulated demonstrating that children are more susceptible to contaminants in their environment. Children's susceptibility stems from four basic conditions: first, when adjusted for body weight, children take in more air, water, and food than adults so they take in more of any contaminants in those media; second, children's behavior can lead to higher exposures because they put their hands in their mouths, play on the ground, and run around outdoors; third, children's physiology is different, especially during infancy, and they detoxify some chemicals less efficiently; finally, their developing brains, reproductive systems, and other organs are more susceptible to permanent disruption that can result in health problems during their life. In fact, research is accumulating that indicates many diseases that occur in adulthood, including neuro-degenerative disorders and many cancers, may have their origins in exposures that occur in the womb and in infancy or childhood.[6] [7]

None of these facts are scientifically controversial. In fact, the National Academy of Sciences (NAS) laid out these issues clearly in their 1993 report, Pesticides in the Diets of Infants and Children.[8] The NAS report found that EPA's existing approach to regulating pesticides failed to address the unique vulnerabilities of infants and children, including the likelihood that infants and children are more susceptible and more highly exposed to pesticides.

Protecting Children: The Example of Pesticide Law

Congress recognized the overwhelming scientific evidence on children's susceptibility by writing child-protective language into the Food Quality Protection Act (FQPA), which passed both Houses of Congress unanimously in 1996.[9] Through the FQPA, Congress required EPA to review the safety of all pesticides used on food crops, and, for the first time in any environmental law, specifically ordered EPA to assure the safety of infants and children. Specifically, pesticide tolerances (for allowable residue levels on food) must ensure to a reasonable certainty that "no harm will result to infants and children from aggregate exposure. . ."[10]

One of the FQPA's most important provisions is that it requires EPA to use an additional ten-fold margin in risk assessments to protect infants and children. EPA must maintain this additional margin to "take into account potential pre– and post–natal developmental toxicity and completeness of the data with respect to exposure and toxicity to infants and children."[11] EPA can depart from this requirement and use a different margin "only if, on the basis of reliable data, such margin will be safe for infants and children."

In ensuring that pesticide residues are safe for infants and children, EPA must base its decision on information about: "food consumption patterns unique to infants and children;" "special susceptibility of infants and children to pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure;" and the "cumulative effects on infants and children of [pesticides] that have a common mechanism of toxicity."[12] By definition, if there are no data or significant gaps in data, there cannot be "reliable data" sufficient to overturn the statutory presumption of an additional ten-fold margin to protect infants and children.

This approach would seem to be a model for how to assure children are protected from toxic chemicals in their food. But there are two important problems.

The first problem is that Congress left the job half-done in 1996. It was important to take steps to require that children be protected from pesticides, but there are many thousands of non-pesticide chemicals that contaminate food, water, air, and consumer products. To this day, there is no legal requirement that EPA take any additional steps to assure that children are protected from these industrial chemicals. Chemicals that are known to disproportionately affect fetuses, infants, or children, such as bisphenol A, phthalates, brominated flame retardants, TCE, and even arsenic remain in a limbo where there is no clear directive to protect children's health. Accordingly, EPA actions to date on these chemicals have failed to adequately protect children.

The second problem is that EPA has honored the child-protective language in the FQPA in the breach. In 2006, an NAS committee, on which I served, reviewed EPA pesticide assessments.[13] The committee reported that out of the 59 pesticides with assessments posted on EPA's website, EPA failed to apply a child-protective factor for 48 chemicals. For five pesticides, the agency applied the full factor of 10 for at least one exposure group and exposure circumstance, such as acute dietary exposure of women of childbearing age. For six pesticides, EPA reduced the factor to 3. In the five cases where the full child factor of 10 was applied, severe developmental toxicity end points, such as multiple malformations and fetal death, were observed in laboratory animals. An updated NRDC analysis focusing on pesticide assessments completed in the past three years found that among 14 recent food-use pesticide assessments, only 2 incorporated the full child-protective factor. Thus there has been little improvement in recent years.

Independent scientists, the EPA's Scientific Advisory Panel (SAP), the EPA Inspector General, and even EPA's own scientific staff, have criticized the Agency's implementation of the FQPA.[14] The SAP expressed concern that the Pesticide Program's approaches "may not be sufficiently conservative, may underestimate the risks to infants and children, and do not adequately identify individuals that may be inherently sensitive to neurotoxicants".[15] A letter from EPA staff scientists to then Administrator Johnson in May 2006[16] stated: "EPA's risk assessments cannot state with confidence the degree to which any exposure of a fetus, infant or child to a pesticide will or will not adversely affect their neurological development." The EPA scientists continued by saying: "We are concerned that the Agency has lost sight of its regulatory responsibilities in trying to reach consensus with those that it regulates, and the result is that the integrity of the science upon which Agency decisions are based has been compromised." A January 2006 Inspector General report points out flaws in the EPA testing process that have yielded a less than "complete and reliable database on developmental neurotoxicity of pesticides... upon which to base any final tolerance reassessment decisions as required by the FQPA."[17] EPA staff scientists specifically requested in their letter that: "Where developmental neurotoxicity studies are absent, it is imperative that the Agency continue to retain the 10-fold safety factor - if not increase it - as a precaution, when making final reregistration decisions for [organophosphate] and carbamate pesticides."

Unfortunately EPA proceeded to finalize their assessment of the organophosphate pesticides in August of 2006 without paying heed to the scientists. The Agency reduced or eliminated the child-protective factor in one-third of the assessments, even though these chemicals are known to be especially toxic to the developing brain, leaving potentially dangerous chemical residues on food, where they can harm infants and children.

I also want to note that Congress inserted child-protective language into the Safe Drinking Water Act amendments of 1996.[18] This law specifies that, when setting maximum contaminant levels (MCLs) for drinking water, EPA must "analyze the effects on groups such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk…" Unfortunately, EPA has neither set a single new MCL, nor has the Agency updated any old MCLs within the last decade. So the child-protective provisions in drinking water law have yet to be implemented. A special concern is the bottle fed infant whose sole source of water can be from the tap and who consumes far more water than other age groups on a bodyweight basis.

We can learn from the example of the FQPA. Congress should apply child-protective requirements to non-pesticide chemicals, and make these requirements even clearer than those in the FQPA, so the Agency must abide by the science. Meanwhile, EPA can re-prioritize children's health protection and can correct the mistakes that have been made in past years that put children at risk.

California Leadership on Carcinogens

A glaring example of EPA's failure to use science to protect children is from cancer-causing chemicals. This is a situation where the State of California has shown real leadership and has adopted scientific principles that protect children's health.

California has done two important things that U.S. EPA has not:

1) California incorporates a factor to protect for prenatal exposure to carcinogens, thereby assuring an extra margin of safety for mothers and children. EPA does not.
2) California considers children to be more sensitive to all carcinogens, unless shown otherwise, whereas EPA's "Supplemental Guidance on Assessing Cancer Risk from Early Life Exposures" limits the child-protective factors to chemicals with a "mutagenic mode of action". In order to decide which chemicals these might be, EPA published a "Framework for Determining a Mutagenic Mode of Action for Carcinogenicity" which requires the Agency to prove that the chemical acts through this specific mechanism based on data which are basically unobtainable for the vast majority of carcinogens.[19] Thus, the two documents together limit any child-protective factors to only a tiny subset of carcinogens.

That last issue – about mutagenic carcinogens – barely passes the laugh test with scientists. EPA's draft Framework has been roundly criticized by not one, but two, of EPA's scientific advisory committees.[20] [21] Specifically, EPA's scientific advisors have pointed out that requiring clear evidence that a carcinogen is also a mutagen creates a powerful disincentive to test chemicals for mutagenicity. In addition, the Framework shifts the burden of proof, such that no child-protective margin is incorporated to protect kids from carcinogens, unless there is clear proof of mutagenicity. Finally, the definition of mutagen in the Framework document is so narrow as to exclude many cancer-causing chemicals that are likely to disproportionately affect children. I am pleased that last fall

EPA announced that it will consider broadening the definition of mutagen, but the fundamental issue remains that the health-protective intent of employing a margin of safety to protect children from carcinogens is undermined by EPA's draft Framework.

In addition, California's Office of Environmental Health Hazard Assessment (OEHHA) has done an analysis of data on carcinogens that have actually been tested during different life stages for their potency in causing cancer. Their analysis of how age at exposure affects cancer showed that early life exposures were more potent for many carcinogens, not just those that have a mutagenic mode of action. Thus, California applies the child-protective factors to all carcinogens unless there is evidence to the contrary.

In addition, OEHHA analyzed differences in how an infant can detoxify and rid themselves of toxic chemicals compared to an adult. That analysis showed that infants and young children are much less able to rid themselves of some common chemicals including butadiene, methylene chloride, trichloroethylene (TCE) and benzo(a)pyrene. Thus, California requires a science-based factor of 30 instead of 10 be applied when assessing the risk from non-cancer toxicity to account for differences in the way young bodies handle chemicals (compared to adults).

California is also developing an approach to address cumulative impacts of environmental exposures that take into account vulnerable populations like infants and children. Since 2008 the state has been convening a workgroup on Cumulative Impacts and Precautionary Approaches and also collaborating with the University of California to develop methods. The goal is to come up with strategies for assessing the multiple exposures, stressors, and vulnerability factors that people face in their homes and communities. This is a tall order, but this important workgroup has made significant progress, and California's forthcoming report will be very useful. According to California's definition,

> *Cumulative impacts means exposures, public health, or environmental effects from the combined emissions and discharges in a geographic area, including environmental pollution from all sources, whether single or multi-media, routinely, accidentally, or otherwise released. Impacts will take into account sensitive populations and socio-economic factors, where applicable and to the extent data are available.*

U.S. EPA should take a careful look at California's approach to protecting children from cumulative impacts in their environment, and should adopt these scientifically-founded strategies in their risk assessments.

National Academy of Sciences Recommendations

In 2008, the National Academies of Science (NAS) released two important reports that made recommendations about ways to better protect children from environmental harm.[22] [23] The report, Science and Decisions, contained the finding: "While consideration of susceptible subpopulations has been included in a number of environmental risk assessments, the level of consideration and incorporation in EPA assessments could be much improved." Recommendations included that:

- EPA develop methods for explicitly considering prenatal exposure in cancer risk assessments. (p. 112)
- EPA systematically evaluate human vulnerability in their assessments. This would include identifying underlying disease processes in the population to which chemicals may be contributing. (p. 9, 146, 181)
- EPA assess background exposures to xenobiotics and endogenous chemicals that may affect the processes by which the chemical produces toxicity and may result in low-dose linearity. (pp. 9, 180)
- EPA develop clear standards and criteria for departing from default assumptions: (1) an evidentiary standard that the alternative is clearly superior (that is, its plausibility clearly exceeds the plausibility of the default) and (2) issue-specific criteria to bridge inference gaps. (pp. 8, 201, 207)
- EPA develop a consistent unified approach for dose response modeling that includes formal and systematic assessment of background disease and exposure, possible vulnerable populations, and modes of action that may affect a chemical's dose-response relationship in humans. (pp. 8-9, Figure 5-8, 179-182)
- EPA incorporate interactions between chemical and non-chemical stressors in risk assessment (in the short term require that they develop a database and default factors that allow for the incorporation of key non-chemical stressors). (pp. 10, 236)
- EPA develop explicitly stated defaults to take the place of implicit ones. "For example, chemicals that have not been examined sufficiently in epidemiologic or toxicologic studies are often insufficiently considered or are even excluded in risk assessments." (pp. 8, 193, 207)

The NAS Report, "Phthalates and Cumulative Risk Assessment, The Task Ahead" described that "infants' and children's physiology, developmental stages, and age-appropriate behaviors all may increase exposure to phthalates.[24] Consequently, they may be especially vulnerable to phthalate exposures during critical stages of growth and development." (p. 18). And also recognized that "There is good evidence that combinations of phthalates and of other antiandrogens produce combined effects at doses that when administered alone do not have significant effect." (p. 97).

The committee went on to make the following recommendations to EPA:

- A physiologically based approach for establishing grouping criteria for phthalates and other antiandrogens is strongly recommended such that all chemicals that can induce some or all of the effects that make up the androgen-insufficiency syndrome should be subjected to cumulative risk assessment. (p 90).
- Assessments based solely on the effects of single phthalates and other antiandrogens may lead to considerable underestimation of risks to the developing fetus. (p. 97).

- The committee's detailed recommendations outlined possible ways of conducting cumulative risk assessments and conceptually could be used to deal with other groups of chemicals, such as neurodevelopmental toxicants (p. 97).

Data Needed to Protect Children's Health

The biggest threat to children's health, however, may not be from chemicals we know, such as lead, mercury, phthalates, and bisphenol A. The biggest threat may be from what we don't know. We are still dealing with the shameful reality that most of the chemicals in our air and water, and even in our children's toys, have not even been tested for their toxicity. I'm not just talking about a lack of testing for effects on infant development; I'm talking about basic testing to see if these chemicals cause genetic damage, neurologic damage, hormonal effects, allergic reactions, and any number of other preventable health effects. Basic safety assessments of all chemicals – not just pesticides – are needed in order to protect children and adults.

A few years ago, I served on a National Academy of Sciences panel on "Toxicity Testing in the 21st Century".[25] The panel issued a final report in 2007 which laid out a vision for how to screen tens of thousands of chemicals in a manner that is cost-effective, sparing of animals, and yet provides the depth of information necessary to assess risks and protect children's health. This approach means that Congress can feasibly require that all chemicals in commerce undergo testing and safety assessments. The scientific tools are within our reach.

Recommendations

EPA should:

1. re-assess the organophosphate pesticides and apply the full child-protective factor to all of these chemicals in order to protect children from adverse effects on neurological development.
2. use the full child-protective factor in most pesticide tolerance decisions as required by Congress.
3. reassess the Framework for a Mutagenic Mode of Action to substantially broaden the carcinogens against which children require special protection.
4. move more quickly to implement the Endocrine Disruptor Screening Program for chemicals in consumer products, air, food, and water.
5. use a child-protective approach, including an additional safety factor and cumulative risk assessment to assess risks of endocrine disrupting chemicals such as phthalates, bisphenol A, and various flame retardants; and move quickly to promulgate regulations to protect children's health.

Meanwhile, Congress should pass comprehensive chemical policy reform that includes testing of all untested chemicals in commerce, requiring manufacturers to prove safety, and the use of an approach that protects children and other vulnerable populations from cumulative risks. Our current system is broken. Only with sweeping chemical policy reform will parents be able to sleep soundly at night, knowing that their children are safe.

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[10] 21 U.S.C. § 346a(b)(2)(C)(ii)(I).

[11] 21 U.S.C. § 346a(b)(2)(C).

[12] 21 U.S.C. §§ 346a(b)(2)(C)(i)(I-III).

[13] Toxicity Testing for Assessment of Environmental Agents: Interim Report, National Academy of Sciences Press, Washington, DC, 2006, p. 132. http://www.nap.edu/openbook.php?isbn=0309100925&page=132.

[14] Melissa L. Phillips. Registering Skepticism: Does the EPA's Pesticide Review Protect Children? Environmental Health Perspectives Volume 114, Number 10, October 2006.

[15] May 25, 1999 SAP meeting.

[16] Letter to Administrator Johnson from Presidents of EPA Unions representing scientists, risk managers, and related staff, May 24, 2006. http://www.panna.org/documents/epaScientistsFqpa.pdf.

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[18] 42 U.S.C. §§ 321, 331, 333, 342, 346a

[19] Framework for Determining a Mutagenic Mode of Action for Carcinogenicity: Using EPA's 2005 Cancer Guidelines and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. http://www.epa.gov/osa/mmoaframework/.

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[24] Phthalates and Cumulative Risk Assessment The Task Ahead, The National Academies Press, Washington, DC, 2008. http://books.nap.edu/catalog.php?record_id=12528.

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Questions from Senator Boxer:

1. EPA has a 1995 policy that says agency staff should consistently and explicitly consider children's risks as part of risk assessments and when setting public health standards. GAO recommended that EPA update this policy using recent science.

Your testimony contains various recommendations from two recent National Academy of Sciences reports that describe better ways to protect children's health.

Could you please describe some of the academy's recommendations and the potential children's health benefits associated with EPA adopting such recommendations? In particular, please note any such potential benefits that could occur in how the Agency conducts its dose-response assessment process.

In 2008, the National Academy of Sciences (NAS) released two important reports that made recommendations about ways to better protect children from environmental harm.[2] [3] The report, Science and Decisions, contained the finding: "While consideration of susceptible subpopulations has been included in a number of environmental risk assessments, the level of consideration and incorporation in EPA assessments could be much improved." Recommendations in the Science and Decisions report included that EPA should:

- Develop methods for explicitly considering prenatal exposure in cancer risk assessments. (p. 112) This recommendation would better protect the public from chemicals that alter cellular or genetic function early in life, thus predisposing people to cancer as adults.
- Systematically evaluate human vulnerability in risk assessments. This would include identifying underlying disease processes in the population to which chemicals may be contributing. (p. 9, 146, 181) Improved consideration of vulnerability would help protect children with underlying developmental disorders from additional exposures to neurotoxic chemicals that could worsen their illness, and would help protect asthmatics from chemicals that can cause allergic sensitization or airway irritation.
- Assess "background" exposures to various natural and synthetic chemicals that may cause a population to exceed any potential threshold of toxicity. (pp. 9, 180) This recommendation would require EPA to consider a variety of chemicals that cause similar endocrine disrupting effects together, to assure that pregnant women, fetuses, and children are protected from a cumulative exposure that could be harmful.
- Consistently use defaults and develop clear standards and criteria for departing from default assumptions, including: (1) an evidentiary standard that the alternative is clearly superior; and (2) specific criteria to bridge data gaps. (pp. 8, 201, 207) The NAS recognized that clear and consistent default assumptions are scientifically based, designed to protect the public with a margin of safety, and that the elimination of these health-protective defaults, or the absence of health-

protective criteria for addressing data gaps, could easily leave the public unprotected from toxic chemicals.

- Incorporate interactions between chemical and non-chemical stressors in risk assessment. (pp. 10, 236) For example, children who are nutritionally deficient in calcium or iron are more susceptible to lead poisoning, so if EPA assumes that all children have a healthy diet, those with nutritional deficiencies would not be protected from the adverse health effects from lead.
- Develop explicitly stated default assumptions to take the place of implicit ones. (pp. 8, 193, 207) For example, data gaps currently generate an implicit assumption of no risk. Chemicals that have not been tested, or for which there are significant data gaps should be assumed to have a certain level of toxicity until shown otherwise. Such an approach would create incentives for companies to fill data gaps, whereas in the current system there is no incentive to fill data gaps because chemicals will not be assessed if there are insufficient data.

The NAS Report, "Phthalates and Cumulative Risk Assessment, The Task Ahead" described that "infants' and children's physiology, developmental stages, and age-appropriate behaviors all may increase exposure to phthalates.[4] Consequently, they may be especially vulnerable to phthalate exposures during critical stages of growth and development." (p. 18). And also recognized that "There is good evidence that combinations of phthalates and of other antiandrogens produce combined effects at doses that when administered alone do not have significant effect." (p. 97).

The committee went on to make the following recommendations to EPA:

- Assessments based solely on the effects of single phthalates and other antiandrogens may lead to considerable underestimation of risks to the developing fetus. (p. 97). This would mean that the total health risk from combinations of chemicals would need to be assessed, thereby better protecting children from real-world situations where they are exposed to mixtures instead of single chemicals.
- A physiologically based approach for establishing grouping criteria for phthalates and other antiandrogens is strongly recommended such that all chemicals that can induce some or all of the effects that make up the androgen-insufficiency syndrome should be subjected to cumulative risk assessment. (p 90). Thus EPA needs to consider mixtures of chemicals – not only including ones that act by the same mechanism, but those that (through various pathways) produce the same health effects such as undescended testicles, birth defects of the penis, low sperm counts, testicular cancer, and other male reproductive effects.
- The committee's detailed recommendations outlined possible ways of conducting cumulative risk assessments and conceptually could be used to deal with other groups of chemicals, such as neurodevelopmental toxicants (p. 97). Thus this NAS report is not just about phthalates or just about endocrine disruptors, but rather it outlines a way for EPA to deal with any groups of chemicals that act in the body in a similar way or on a similar organ system. This would mean that EPA should look at groups of chemicals together that interfere with normal brain

development, to assure that children are protected from combined exposures that can cause harm.

2. Your testimony describes how the State of California has shown leadership in safeguarding children's health by using certain scientific risk assessment principles aimed at protecting children's health.

Could you please describe some of these principles, and whether they provide more protection than EPA currently provides during risk assessment that the agency uses to develop public health standards?

The State of California has shown real leadership in protecting children's health, and has taken two particularly important actions with regard to cancer-causing chemicals: (1) California assures an extra margin of safety for mothers and children by incorporating a factor to protect for prenatal exposure to carcinogens. (2) California considers children to be more sensitive than adults to all carcinogens, unless shown otherwise.

In contrast, EPA's "Supplemental Guidance on Assessing Cancer Risk from Early Life Exposures" limits the child-protective factors to chemicals with a "mutagenic mode of action". In order to decide which chemicals these might be, EPA published a draft "Framework for Determining a Mutagenic Mode of Action for Carcinogenicity" which requires the Agency to prove that the chemical is a mutagen based on data which are basically unobtainable for the vast majority of carcinogens.[5] Thus, the two documents together limit any child-protective factors to only a tiny subset of carcinogens – those that are proven mutagens. EPA's scientific advisors have criticized the draft, pointing out that requiring clear evidence that a carcinogen is also a mutagen creates a powerful disincentive to test chemicals for mutagenicity.[6] In addition, the Framework shifts the burden of proof, such that no child-protective margin is incorporated to protect kids from carcinogens, unless there is clear proof of mutagenicity, so an absence of data means that children are not given any added protection.

California's Office of Environmental Health Hazard Assessment (OEHHA) has done an analysis of carcinogens that have actually been tested during different life stages for their potency in causing cancer. Their analysis of how age at exposure affects cancer showed that early life exposures were more potent for many carcinogens, not just those that have a mutagenic mode of action. Thus, California applies the child-protective factors to all carcinogens unless there is evidence to the contrary.

In addition, OEHHA analyzed differences in how an infant can detoxify and rid themselves of toxic chemicals compared to an adult. That analysis showed that infants and young children are much less able to rid themselves of some common chemicals including butadiene, methylene chloride, trichloroethylene (TCE) and benzo(a)pyrene. Thus, California requires that a science-based factor of 30 instead of 10 be applied when assessing the risk from non-cancer toxicity to account for differences in the way young bodies handle chemicals (compared to adults).

California is also developing an approach to address cumulative impacts of environmental exposures that take into account vulnerable populations like infants and children. Since 2008 the state has been convening a workgroup on Cumulative Impacts and Precautionary Approaches and collaborating with the University of California to develop methods to assess cumulative impacts. The goal is to come up with strategies for assessing the multiple exposures, stressors, and vulnerability factors that people face in their homes and communities. This workgroup has made significant progress, and California's forthcoming report will be very useful.

U.S. EPA should take a careful look at California's approach to protecting children from carcinogens, considering how children detoxify non-carcinogens compared to adults, and addressing cumulative impacts, and should adopt these scientifically-founded strategies in their risk assessments.

3. Dr. Solomon, the committee received testimony about links between childhood exposure to environmental contaminants such as chemicals and the adult onset of diseases.

Do you think that a stronger government effort to identify the likelihood and prevalence of such links is needed? In your opinion, what public health benefits could be achieved by identifying those links?

There is a remarkable amount of scientific information that has emerged in recent years showing that early life exposures to infectious agents, drugs, or toxicants, can permanently alter gene expression or hormonal activity.[7] These alterations can then predispose individuals to cancer or other disease many years later. This area of science is an extremely important one for government-funded research, which would help to further identify the conditions in which lifelong alterations in gene or hormonal expression can occur. This research could be funded by the National Institutes of Health or by the EPA. In addition, the National Children's Study[8] is designed to research this exact set of important issues, so it deserves ongoing support. The National Children's Study could ultimately help uncover (and thereby prevent) environmental causes of disorders such as autism, learning disabilities, asthma, miscarriage, birth defects, and childhood cancers.

In addition to basic research on this issue, however, there is also a need to develop biological assays that can screen for these types of effects at a cellular or sub-cellular level. For example, assays that identify alterations in gene expression or estrogenic effects can be used to screen thousands of chemicals for their potential to alter normal gene and cellular function. EPA has developed the ToxCast program,[9] and EPA is collaborating with the NIEHS on the Tox21 program,[10] both of which are designed to develop high-throughput assays to identify chemicals that alter basic cellular functions in a way that can lead to disease years later.

The use of screens to detect genetic or cellular perturbation was recommended by the National Academy of Sciences as the appropriate future direction for chemical toxicity testing.[11] Implementing the vision of the NAS report on Toxicity Testing for the 21st

Century will help with many of the current roadblocks in environmental health today, and thereby would bring major public health benefits, for example:

- Rapid cell-based and subcellular assays would easily allow screening of tens of thousands of chemicals per year, thereby helping to address the massive backlog of untested chemicals in the TSCA inventory.
- These types of assays would reduce animal testing and offer cost savings compared to traditional toxicology approaches.
- Most animal toxicology tests currently used for regulatory purposes are not designed to identify early-life alterations in gene or cellular function and later onset of disease, because the animals are rarely exposed early in life and then kept alive for long enough for delayed disease to manifest.
- Well-designed cell-based or subcellular assays could be sensitive ways of identifying subtle alterations in biologic functions that are predictors of later disease.
- Once these assays have been found to be reliable, they can be used as a basis for regulatory action, which can protect public health by stopping the perturbation of the biological pathway and thereby preventing the adverse public health events years later.

In my opinion, the new science linking early life exposure and adult disease, combined with the new scientific tools that allow rapid chemical screening, represents a major scientific breakthrough. In the coming years, I expect that tools will exist to screen large numbers of chemicals for their ability to disrupt basic biological pathways, and at the same time, science will have shown what diseases these disruptions can cause over time. The result will be the ability to more effectively identify chemicals that can cause disease, and take action to prevent disease in humans.

Question from Senator Vitter:

1. What kind of opportunities do you believe exist for better coordination between EPA and the medical community?

In general, the medical community tends to interact more frequently with the Health and Human Services Agency than with the EPA. When environmental health issues arise, in my experience, local physicians often start by contacting local health departments, the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR). Although all of these are important resources for the medical community, EPA is also an under-appreciated resource.

EPA and ATSDR have worked together for many years in an important collaboration to fund Pediatric Environmental Health Specialty Units (PEHSUs) around the country.[12] These PEHSUs are based in each of the EPA regions, and include collaborations of pediatricians and toxicologists who work together to educate pediatricians about environmental health, offer clinical consultations, and respond to calls from the public, health care providers, and local agencies. The PEHSUs are an excellent model of collaboration between EPA, CDC/ATSDR, and the medical community. Unfortunately the PEHSUs operate on a very marginal budget, and have not had much capacity for expansion given the lack of resources. As a result, many of the PEHSUs do not reach into more rural areas, or into states outside those where they are based.

Over the past few weeks, in my clinical capacity at the University of California San Francisco (UCSF), I have been working with EPA Region 9 Emergency Response and the UCSF PEHSU on a mercury exposure situation in the San Francisco Bay Area. The EPA Emergency Response unit sent out a rapid response team within hours of being called, and their tests helped to identify and remove the exposure source. As a result of this positive experience, I am arranging to bring EPA Emergency Response personnel to UCSF to educate the faculty and residents about what they do. Perhaps in the future, our medical students or residents may accompany the emergency response teams to assist in their investigations.

The medical community can be an important resource for EPA. Local clinicians can sometimes identify important local environmental health issues. For example, alert clinicians have reported significant cancer and other disease clusters that required further investigation; clinicians in the Gulf Coast reported concerns about high rates of respiratory symptoms which alerted the Agencies to the serious mold problem after the flooding, as well as to the health threats from formaldehyde-contaminated FEMA trailers.

In 1998, EPA launched the "National Strategies for Health Care Providers Pesticide Initiative".[13] I participated in an expert group that created the implementation plan for this five-year initiative. Although there is a major need for better education of health care providers around the prevention, recognition, and management of pesticide poisonings (and other environmental health issues), this EPA effort unfortunately has not continued.

The need for improvements in health care provider training has been expressed by health provider groups as well as government and community organizations. In 1994, the American Medical Association adopted a resolution urging Congress, government agencies, and private organizations to support improved strategies for the assessment and prevention of pesticide risks. These strategies included systems for reporting pesticide usage and illness, as well as educational programs about pesticide risks and benefits. In addition, two Institute of Medicine committees have dealt with the general issue of environmental health education, focusing on nurses and physicians.[14] Both committees recommended an integration of environmental health concerns throughout the various stages of training and clinical practice for health care providers.

There is a serious shortage of physicians in the United States with training in public health and environmental health. A 2007 IOM report concluded that approximately "1,350 properly prepared public health physicians are needed every year to replace those leaving the existing workforce. Therefore, once the desired number of 20,000 public health physicians in governmental agencies is reached, the system must have the capacity to train at least 1,350 new physicians per year to replace those leaving public health careers."[15] In my opinion, it would be useful for EPA to do more outreach to the medical community around environmental health issues, and to help support better training for health care providers on environmental health.

I hope that this additional information is useful to the Committee as it continues its deliberations on these important public health issues.

Sincerely,

Gina Solomon

Gina M. Solomon, M.D., M.P.H.
Senior Scientist

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[1] Framework for Determining a Mutagenic Mode of Action for Carcinogenicity: Using EPA's 2005 Cancer Guidelines and Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. http://www.epa.gov/osa/mmoaframework.

[2] Science and Decisions: Advancing Risk Assessment, National Academies Press, Washington, D.C. 2008. http://dels.nas.edu/dels/viewreport.cgi?id=5545.

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[4] Phthalates and Cumulative Risk Assessment The Task Ahead, The National Academies Press, Washington, DC, 2008. http://books.nap.edu/catalog.php?record_id=12528.

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[14] Division of Health Promotion and Disease Prevention. Role of the Primary Care Physician in Occupational and Environmental Medicine. National Academies Press, Washington DC, 1988.

[15] Institute of Medicine. Training Physicians for Public Health Careers, National Academies Press, Washington DC, 2007.

Senator KLOBUCHAR. Thank you, Dr. Solomon.

Dr. Bearer.

STATEMENT OF CYNTHIA BEARER, M.D., PH.D., FAAP, DIVISION CHIEF, NEONATOLOGY, UNIVERSITY OF MARYLAND SCHOOL OF MEDICINE; CHILDREN'S ENVIRONMENTAL HEALTH NETWORK BOARD CHAIR

Dr. BEARER. Thank you, Senator Klobuchar.

I am a practicing neonatologist, which means that I take care of the sickest of the babies, the newborn babies. I am also a wife and mother, and my son, Matthew, is in the audience today.

Senator KLOBUCHAR. Welcome, Matthew. Where are you? I can tell you want me to call you out. You are lucky I did not make you stand.

[Laughter.]

Dr. BEARER. I am currently Professor and Division Chief of Neonatology at the University of Maryland, and I am here today, though, as the Chair of the Board of the Children's Environmental Health Network.

The Network commends Senators Boxer and Inhofe for holding this hearing and to you for running it today and for their ongoing interest in environmental risks to children.

I ask that my full statement be submitted for the record.

The Network's mission is to promote a healthy environment and to protect the fetus and child from environmental health hazards. I urge the Committee to embrace its role in ensuring that all children grow up in healthy environments. I will discuss three overarching tenets.

My first tenet is that the basic scientific facts of pediatric environmental health need to be incorporated into the policies and programs in this Committee's jurisdiction. Children, as we heard this morning, are not just little adults. They have unique vulnerabilities and susceptibilities. Because their systems are developing an exposure that causes little or no damage to adults may lead to irreversible damage to children and the adults they become.

Children are exposed every day to a mix of chemicals, most of them untested for their effects on developing systems, as Dr. Solomon just noted. Policymakers could—and must—do a better job of assessing the role that environmental toxicants have on affecting the current and future health of developing human beings. The predominant and worrisome assumption is that potential hazards are innocent until proven guilty.

One example is bisphenol A, or BPA, which is widely used in consumer products. Only recently have scientific studies shown that BPA causes harm. These studies have come long after massive population exposure has already occurred, with more than 90 percent of our citizens having BPA in their bodies. As a result of these reports BPA is being phased out of products used in the neonatal intensive care unit at the University of Maryland Hospital for Children.

BPA is just one chemical that is ubiquitous in our environment and in our bodies. Parents understandably ask, how did we allow these substances to get into our children's bodies when we know so little about them? I do not know how to answer them.

Most industrial chemicals are regulated through the Toxic Substance Control Act, or TSCA, which was enacted in 1976. However, EPA comprehensively regulates very few chemicals under TSCA. We need to protect the health of children through our chemical regulatory decisions.

My second tenet is that children's health and healthy children must be an ongoing priority for this and every Administration. A series of forward looking policies were adopted in the 1990s. Over time their original successes have stalled. Previously, leadership of an Interagency Task Force by the EPA Administrator and the Secretary of DHHS galvanized efforts across the Government. We need such a catalyst again in order to regain momentum.

The Network believes that key components of the 1997 Executive Order on Children's Environmental Health, such as the Interagency Task Force that it created, should be put into statute. Such legislation must also ensure that other key agencies handling childcare and related issues, most notably the Department of Education, are actively engaged.

I want to highlight the importance of the EPA's Office of Children's Health Protection in this process. The Network feels that it must have a robust presence within EPA in steering policy and science initiatives for the good of protecting children. Their advisory committee, the CHPAC, plays a critical role in providing advice and feedback to the EPA.

My third tenet is that protection of children's environmental health must occur indoors. One focus on interior environments such as homes, childcare centers and schools is necessary. For example little is known about the environmental health status of our childcare centers where 60 percent of children from 1 month to 5 years of age spend more than 40 hours per week. Most people do not know that there is no agency authorized to intervene to protect children from environmental hazards in daycares, pre-schools or schools.

The Occupational Safety and Health Administration does not protect pre-school or school children. Thus every day we require or children to spend hours in environments that are not required to be healthy and where they and their parents have no options, alternatives or recourse.

The Network also commends the EPA for its existing healthy school activities. We are especially supportive of the proposed Clean, Green and Healthy Schools Initiative. If we work to ensure that the many environments that make up our children's world are healthy and promote well-being we will improve the health of our children and the adults they will become.

Thank you for the opportunity to testify. I would be happy to answer any questions.

[The prepared statement of Dr. Bearer follows:]

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Testimony of Cynthia Bearer, M.D., Ph.D., FAAP
CEHN Board Chair
Environment and Public Works Committee
United States Senate
March 17, 2010

Thank you for the opportunity to testify before you today. My name is Cynthia Bearer. I am a pediatric neonatologist and I currently serve as the Mary Gray Cobey Professor and Division Chief of Neonatology at the University of Maryland. I am here today as the Chair of the Board of the Children's Environmental Health Network. We commend Senators Boxer and Inhofe for holding this hearing today and for your ongoing interest in environmental risks to children.

The Network is a national organization whose mission is to promote a healthy environment and to protect the fetus and the child from environmental health hazards. The Network's Board and committee members include internationally-recognized experts in children's environmental health who serve on key Federal advisory panels and scientific boards.

We at the Network recognize the long leadership that you, Madame Chair, have provided in protecting children from environmental hazards. You authored the first legislation in Congress to recognize children's unique vulnerabilities and susceptibilities to toxicants in their environment and to propose necessary improvements to our regulatory framework to protect our children. Your leadership in this field has not wavered.

I urge the Committee embrace its role in assuring that all children grow up in healthy environments.

One component of creating healthy environments for children is for the Committee to assure that the basic facts of pediatric environmental health are incorporated into all of the policies and programs in its jurisdiction. These facts, supported by sound science as well as a solid consensus in the scientific community, include:

- Children's bodies and behaviors differ from adults. In general, they are more vulnerable than adults to toxic chemicals.
- Children are growing. Pound for pound, children eat more food, drink more water and breathe more air than adults. Thus, they are likely to absorb higher doses of substances from their environment than do adults. Children have higher metabolic rates than adults and are different from adults in how their bodies absorb, detoxify and excrete toxicants.
- Children's systems, including their nervous, reproductive, digestive, respiratory and immune systems, are developing. This process of development creates periods of vulnerability when

environmental exposures may result in irreversible damage while the same exposure to a mature system may result in little or no damage.

- Children's behavior patterns can lead to different patterns of exposures. For example, they exhibit hand-to-mouth behavior, ingesting whatever substances may be on their hands, toys, household items, and floors. Children play and live in a different space than do adults. For example, very young children spend hours close to the ground where there may be more exposure to toxicants in dust, soil, and carpets as well as low-lying vapors such as radon, mercury vapor or pesticides.
- Children have a longer life expectancy than adults; thus they have more time to develop diseases with long latency periods that may be triggered by early environmental exposures, such as cancer or Parkinson's disease.

These concepts may be more important today than they were 50 or 100 years ago because the world in which today's children live has changed tremendously from that of previous generations. There has been a phenomenal increase in the substances to which children are exposed. According to the EPA, more than 83,000 industrial chemicals are currently produced or imported into the United States. Every day, children are exposed to a mix of chemicals, most of them untested for their effects on developing systems. Many of these chemicals are readily passed across the placenta to the fetus, to the infant via breast milk or through skin, or via food, toys and other children's products. Many of these chemicals are also ingested in food and water or through the lungs.

As epidemiologists see increasing rates of asthma, learning disabilities, and childhood cancers; as parents seek the causes of birth defects; as researchers understand more and more about the fetal origins of disease, policy makers must do a much better job of taking into account the role of environmental toxicants in affecting human health.

Emerging science shows the need to act with caution to protect children from toxics

Unfortunately, the traditional approaches used for setting standards, regulations and guidelines have been to use a one-size-fits-all template, and that template is usually the healthy adult male. The predominant assumption in our regulatory approach to environmental protection is that potential hazards are innocent until proven guilty.

One example is Bisphenol-A, or BPA. Bisphenol-A is widely used in consumer products such as plastic baby bottles, toys, plastic water bottles, in thermal paper production, and the linings of metal food cans. BPA, originally developed as a replacement for the female hormone estrogen, is an endocrine disrupter. More than a million pounds are manufactured in the U.S. every year. Yet, we only recently have seen the publication of independent studies that have found harm, most disturbingly alterations of neurological development in early life.

Studies indicate that Bisphenol A can be found in more than 90% of the U.S. population. BPA is just one chemical that is ubiquitous in our environment and in our bodies. Parents understandably ask: "How did we allow these substances to get into our children's bodies when we know so little about them?"

The U.S. Environmental Protection Agency (EPA) regulates thousands of industrial chemicals through the Toxic Substances Control Act (TSCA) (15 U.S.C. s/s 2601 et seq.). This statute was adopted by Congress in 1976.

As far back as 1994, the then-General Accounting Office (GAO) concluded that EPA regulates few chemicals under TSCA, listing only five (PCBs, chlorofluorocarbons, dioxin, asbestos and hexavalent chromium).

One of these -- PCBs -- was required to be regulated by the statute and led to one of the only two cases in which the EPA used TSCA to attempt a comprehensive approach to the regulation of chemicals.

The other Agency effort to undertake a comprehensive approach to the regulation of a chemical was for asbestos. After 10 years of building its case, the courts ruled that EPA was unable to make a supportable finding under TSCA for regulating asbestos -- a known human carcinogen which has caused at least 200,000 deaths in the U.S.

Some of the concepts that must be adopted if we are to replace TSCA with a statute that protects children include:

- Health protection of children as the basis for chemical regulatory decisions.
- A strong safety standard.
- A high priority on protecting children's health and that of other vulnerable populations.
- Don't allow exposure to chemicals that do not meet core information requirements.
- Shift the burden of proof to industry to demonstrate safety of a chemical.
- Establish a process with deadlines and commitment to timeliness.
- Reward the development of science-based information about chemicals and exposures.
- Provide an additional safety margin for children, pregnant women, the fetus, nursing women, and women of child-bearing age.
- Prohibit health information from being declared as "confidential business information"

A reformed TSCA should protect children from chemicals that interfere with their hormone systems, such as BPA, and from unknown or emerging threats to health such as nanotechnology and perfluorinated chemicals. The Agency must also be at the forefront of using promising new scientific methodologies, such as epigenetics, genomics and metabolomics, to more expeditiously and accurately protect the health and development of our most vulnerable. When we protect the most vulnerable, we protect everyone.

Children's health and healthy children must be an on-going priority for this and every Administration

Since the Network's creation in 1992, great leaps forward have been made.

Most recently, the EPA has taken many steps that will move us toward healthier environments for children and we commend Administrator Jackson for her leadership. This includes better protections for farmworkers and farmworker children from pesticides and improving pesticide labeling as well as initiatives to improve environmental health in schools. We believe that the Agency will continue to make strides forward to better protecting children.

However, Administrator Jackson and her Agency face a difficult challenge of regaining lost momentum.

In 1997, President Clinton issued Executive Order 13045, to protect children from environmental health and safety risks, resulting in notable successes and promising initiatives, most notably an effective interagency task force. Since 1995, EPA has a policy requiring the Agency to consistently and explicitly evaluate environmental risks of infants and children in all risk assessments, risk characterizations, and in setting environmental and public health standards. Since 1997, the Office of Children's Health Protection (OCHP) has led the Agency's efforts to protect children from environmental hazards.

Over a number of years, the Executive Order was weakened and its inter-agency task force is now moribund. The EPA policy has not been followed routinely and consistently. For example, the Agency's updated cancer supplemental guidance is not applied across-the-board, as EPA's own Science Advisory Board (SAB) recommended and which would result in better protecting children from carcinogens. Once highly effective and well-regarded, the OCHP has struggled with staffing and funding issues as well as the dilution of its mission.

The interagency task force established under the Executive Order engendered collaboration across agencies critical to addressing children's environmental health and safety issues like asthma, lead poisoning, childhood cancer, injury prevention and establishment of the National Children's Study. These have involved a myriad of agencies (e.g., EPA, HHS, HUD, Education, CPSC and others). Leadership of the task force by the EPA Administrator and the Secretary of HHS catalyzed efforts across the government.

First, the Network believes that key components of this Executive Order, such as the interagency task force, should be put into statute and would be very valuable in protecting children.. Doing so would make it more difficult for agencies to ignore it in the future

Such legislation must also assure that other agencies with jurisdiction over environments where children spend much of their time -- most notably the Department of Education -- are active and engaged partners. This also includes those offices handling child care and related issues.

As you know, leadership at senior levels is critical to making changes and getting things done. Thus, the knowledge of and commitment to children's environmental health should be an important qualification for all political appointees to relevant posts, as well as those in career posts. We commend you, Madame Chair, for using confirmation hearings to put appointees on the record regarding these concerns. We hope that this becomes a tradition for this Committee and among your colleagues.

The Network believes that the OCHP and its advisory body, the Children's Health Protection Advisory Committee (CHPAC), has been and should continue to be the conscience for children's health protection in EPA, as well as a spotlight to highlight accomplishments, shortfalls, and opportunities. Thus, the CHPAC and possibly OCHP itself might be created in statute, with assurances that a substantial portion of CHPAC appointees be independent experts in pediatric environmental health.

In sum, the Network urges the Committee to direct the Agency to assure that all of its activities and programs -- including regulations, guidelines, assessments and research -- specifically consider children. The Agency's work must always assure that children and other vulnerable subpopulations are protected, especially poor children, minority children, farmworker children, and others at risk.

Protecting Children's Environmental Health, Indoors

A focus on the home environment, including the pollutants and products to which children are exposed, is necessary. Young children spend hours close to the ground where there may be more exposure to toxicants in dust, soil, and carpets as well as in low lying vapors such as radon or pesticides. Normal child development includes a great deal of hand-to-mouth behavior. This behavior provides another potent avenue for exposure to a variety of environmental chemicals.

Millions of preschoolers enter care as early as six weeks of age and can be in care for more than 40 hours per week. Yet little is known about the environmental health status of our child care centers nor how to assure that they are protecting this important group of children. Environmental health is rarely if ever considered in licensing centers or training child care professionals. The Network is one of the few entities who conduct educational and assessment activities at child care centers, often supported by some EPA regional offices. Much more needs to be done to assure that this environment is a healthy one.

The EPA and many others are working to improve school environmental health, though, again, much more needs to be done. Each school day, about 54 million children and nearly 7 million adults —20% of the total U.S. population—spend a full week inside schools. Unfortunately, many of the nation's 121,000 public and private K-12 school facilities are shoddy or even "sick" buildings whose environmental conditions harm children's health and undermine attendance, achievement, and productivity. In 1996 GAO reported that more than 13 million children were compelled to be in schools that threatened their health and safety.

Most people do not know that **no** agency is authorized to intervene to protect children from environmental hazards in schools. The Occupational Safety & Health Administration does not protect schoolchildren. It also doesn't cover a school employee unless the employee's job description specifically mentions the handling of hazardous chemicals. Thus, every day we require our children to spend hours in an environment where they and their parents have no options, alternatives or recourse if the environment is not healthy.

Thus, Madame Chair, we commend you for the leadership you have shown in fighting for healthier school environments, such as monitoring for air toxics around schools and addressing contaminants found in drinking water at some schools.

The Network also commends the EPA for its existing healthy schools activities, such as the Indoor Air Quality Tools for Schools program and other voluntary activities. We are especially supportive of the proposed Clean, Green and Healthy Schools Initiative in the EPA's FY 2011 budget. Under this initiative, EPA will co-lead an interagency effort in integrating existing school programs including asthma, indoor air quality, and enhanced use of integrated pest management. Among other activities, there will be increased air toxics monitoring for schools.

The Network believes that further steps to improve the school environment require examining other environmental hazards in school, such as pesticides, cleaning solutions, and other products.

For all indoor environments -- home, child care, and school -- indoor air quality is an ongoing challenge. The air within homes and other buildings can be more seriously polluted than the outdoor air in even the largest and most industrialized cities. Since children spend between 80 and 90 percent of their time indoors, poor indoor air quality may post a greater risk to their health than exposure to outdoor air pollution.

Yet parents, caregivers, teachers, and facility managers have no guidance as to when the line between healthy and unhealthy indoor air is crossed. The Network acknowledges that the challenge is great, but believes that the Agency should be directed to work toward standards for indoor air quality.

In brief, in order to be healthy you have to live in a healthy place. If we work to assure that the many environments that make up our children's world are healthy, we will improve the health of our children.

In conclusion, the ultimate question is: are we committed to protecting our children from environmental health threats?

Waiting for certain evidence of harm means that a generation or more of children would be placed unnecessarily at risk of life-long, irreversible damage. For every exposure to a potentially harmful chemical that we eliminate, we reduce the risk of disease or disability, and help to assure that our children will have long, healthy and productive lives.

Thank you for the opportunity to testify on these critical issues, and thank you for your outstanding leadership on behalf of children. I would be happy to answer any questions you may have.

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Responses to Questions for the Record

Environment and Public Works Committee
United States Senate
From March 17, 2010 Hearing
Submitted by the Children's Environmental Health Network
Cynthia Bearer, M.D., Ph.D., FAAP, CEHN Board Chair

Senator Barbara Boxer

1. Dr. Bearer, you testify that EPA's Office of Children's Health Protection and the Children's Health Protection Advisory Committee are really "the conscience for children's health protection in EPA". Could you please describe why you believe they are the conscience of the agency and how they can best help to provide strong leadership on this important issue?

Though it is too seldom recognized as such, the EPA was created as a health agency -- its mission is to protect human health as well as to protect the environment. Since children can be more susceptible to harm from environmental toxicants than adults, when EPA protects children and other vulnerable populations, it protects all of us.

Thus, the parts of the Agency which are focused on children -- the Office of Children's Health Protection and the Children's Health Protection Advisory Committee -- provide a valuable compass for all Agency activities, as well as an important lens through which all Agency actions should be considered.

Thus, these entities need adequate resources to assure they can provide the appropriate focus on children and their developing systems for the entire Agency. Just as importantly, these entities require adequate stature and authority to assure that their guidance is followed and that all Agency actions are considered in the light of their impact on children and, ultimately, can be shown to be protective of children.

Other important but unrelated functions should be removed from the OCHP to allow the office to maintain its focus.

2. Dr. Bearer, you testify about the importance of protecting children's health at schools. As you know, this is an issue that I also take very seriously. How would you describe the current Administration's initiatives to protect children's environmental health at schools?

Madame Chair, your long commitment to and strong leadership on behalf of protecting children's environmental health is well known.

The Network applauds the actions undertaken by the Administrator regarding air toxics near schools and school siting issues. The Network strongly supports the Clean, Green and Healthy Schools Initiative. It's vital that "healthy" is in this initiative, along with "clean" and "green."

We're glad that the Administration recognizes, as others have said, that a green school is not necessarily a healthy school. Worthy efforts -- such as increasing insulation at a school to improve energy efficiency -- can have unintended harmful side effects, such as creating or exacerbating indoor air quality problems, if health is not also considered at the same time.

Creating green and healthy schools and child care facilities means that our children can reach their full potential. With clean, green and healthy facilities,

- Children are healthier
- Educational outcomes such as attendance and achievement improve
- Health care costs decrease
- The need for special education services is reduced
- Green jobs are created in thousands of local communities
- Energy demands decrease and the use of renewables increases; and
- A workforce skilled in "green and healthy" facility construction and maintenance is created.

As a result, our communities are improved in a variety of dimensions. Thus, the Network is delighted that the Administration's focus is in all three areas. We encourage this initiative to be a part of a revitalized interagency task force on children's environmental health. One goal of this initiative should be to develop a coordinated Federal strategy to work with states to accelerate Federal and state actions promoting healthy school and child care environments for all children.

We support not only the Administration's proposed $6.2 million increase (to $6.3 million) to create healthier school environments for all children but we also support additional funds to restore funding to the child health and schools programs cut by the previous Administration.

Another important environment, where millions of our youngest children spend 40 or more hours per week -- the child care setting -- should also be incorporated into this initiative. The Network has identified child care facilities as a missed opportunity to address children's environmental health. The Network has launched a successful program to fill this gap and welcomes additional initiatives to protect these most vulnerable children.

Senator David Vitter

1. What kind of opportunities do you believe exist for better coordination between EPA and the medical community?

To foster better coordination, within the EPA, the Agency should increase the number of employees who are physicians, nurses (especially pediatricians and pediatric nurses), and epidemiologists. Such professionals should be serving on advisory panels as a matter of routine, but this participation alone is insufficient. By developing and staffing positions specifically requiring qualified professionals in these fields, EPA would have the needed internal expertise on children's health, children's health research, and epidemiologic studies. Without such in-house knowledge, the valuable input from health professionals on advisory committees, and even the framing of issues and questions presented to these advisory committees, are not maximized. The Agency needs staff who are comfortable with children's health issues and the tools to examine them for the health benefits.

Improved inter-agency coordination is necessary. In the past, through the Interagency Task Force on Children's Environmental Health and Safety and the associated Senior Staff Policy Committee, EPA worked very closely with the HHS Office of the Secretary, the Surgeon General's Office, the CDC, and NIEHS. These relationships offered EPA entree to the medical community. The reinvigoration of these two committees will foster greater contact between EPA and the medical and health professions.

Externally, all health professions can do a better job of assuring that their members are trained in the health impacts of environmental exposures, although some professions are further along in this process than others. EPA can provide leadership and support in this area.

Other specific ideas to foster improved coordination include:

- Recruit physicians and nurses to staff the Office of Children's Health Protection
- Assure that pediatric health professionals serve on the Children's Health Protection Advisory Board.
- Work with organizations of health professionals to distribute information to their members. For example, in the past, the Agency provided funding to support distribution of the Handbook of Pediatric Environmental Health, which is published by the American Academy of Pediatrics..
- Initiate on-going efforts to hire physicians and nurses through the Public Health Service.
- Establish fellowships for members of different health and medical specialties at the Agency.
- Work with HRSA and the Public Health Service to educate health professionals about children's environmental health issues.

Senator KLOBUCHAR. Thank you very much, Dr. Bearer.

Dr. Schettler.

STATEMENT OF TED SCHETTLER, M.D., M.P.H., SCIENCE DIRECTOR, SCIENCE AND ENVIRONMENTAL HEALTH NETWORK

Dr. SCHETTLER. Thank you very much, Madam Chair, and thank you for the opportunity to testify here today.

I am Ted Schettler, and I am the Science Director of the Science and Environmental Health Network. I am a physician, and I also have training in public health and environmental medicine.

We have heard from a number of people today that developing children are uniquely vulnerable to environmental exposures. I would like to add to that that early life exposures can also increase the risk of chronic degenerative diseases in adulthood so that while we are protecting our children, we are also lowering the risk of disease later in life.

We have also heard that during the 1990s it appeared that EPA was taking steps to address many of the unique aspects of children's environmental health, but since then some of these efforts have fallen short. I would like to just add two examples from my own experience to illustrate this.

The first has to do with the potential for some commonly encountered chemicals to disrupt the function of hormones and other chemical messengers that are important during child development. These chemicals are called endocrine disrupters.

During the 1980s and 1990s it became apparent that reproduction and development of many species of wildlife were being affected by exposures to these chemicals, and laboratory findings confirmed these outcomes. Many scientists then began to wonder whether the increasing incidence of cancer of the testes, prostate, breast, birth defects of the male reproductive tract, lower sperm counts, behavioral disorders and other abnormalities in humans might be explained in part by similar exposures.

So, in 1996 the EPA created the Endocrine Disruptor Screening and Testing Advisory Committee in response to a congressional mandate, and the EPA was directed to develop a screening program to determine whether certain substances may have endocrine disrupting effects. This was supposed to be implemented by 1999. I served on that Advisory Committee, and we delivered consensus recommendations by the statutory deadline in 1998.

Unfortunately, thereafter EPA missed deadline after deadline and became bogged down in an endless set of validation exercises that remain unfinished today. Meanwhile, thousands of chemicals in consumer products, food, water and air have not been tested for endocrine disrupting properties.

Recently, the Endocrine Society, the American Medical Association and the American Chemical Society have called for reducing exposure to endocrine disruptors as well as more rapid advancement of the screening program. Sadly, the EPA is a decade late, and we are still waiting.

My concerns about human exposures to commonly encountered chemicals are not limited, however, to endocrine disruptors. As we have also heard flaws in the Toxic Substances Control Act have allowed thousands of untested chemicals to remain in commerce with limited or no toxicity information.

A second example is the failure of EPA to require adequate evaluation of the impact of pesticides and other chemicals on brain development. The agency has the authority to require those data from pesticide registrants but historically has been reluctant.

In the 1990s, the EPA finally asked for developmental neurotoxicity testing of a group of pesticides called organophosphates, which are notoriously toxic to the brain. But if we thought that we were finally going to see more regular requirements for this information we were sadly disappointed in 2007 when EPA registered the fumigant methyl iodide for use without it. This chemical is an extremely toxic chemical. It causes severe nervous system toxicity in adults who are accidentally exposed. Unfortunately, effects on the developing brain have never been studied.

In my written testimony I have described why I and others believe we must be concerned. EPA's rationale for not requiring the data on this pesticide is based on an untested hypothesis for which there is little evidence.

The Department of Pesticide Regulation in California carried out its own risk assessment of methyl iodide and set it out for external review by a scientific review committee. In its final report that committee not only expressed concern about the likelihood of human exposure when this chemical is used in agriculture but also said—and I am quoting—an equally important element in our review was the data that we would have wished to assess but that was insufficient or nonexistent altogether. The lacunae in our knowledge about methyl iodide are particularly wide and deep in relation to key aspects of its potential toxicity such as neurodevelopmental effects. That is the end of the quote.

Wide and deep data gaps with respect to this chemical's effect on the developing brain. Yet the EPA registered it for use.

So, in conclusion, some efforts to protect children's health that were taking hold seem to have slowed and even been abandoned. Developing children continue to be exposed to environmental chemicals without adequate safety assessment, many of these under the authority of the EPA. Meaningful TSCA reform and EPA's exercise of its existing authority are essential in order to protect developing children—and really people of all ages—from the impacts of exposure to hazardous chemicals.

Thank you, Madam Chair.

[The prepared statement of Dr. Schettler follows:]

Testimony of

Ted Schettler MD, MPH

Science Director
Science and Environmental Health Network

HEARING ON EPA'S EFFORTS TO PROTECT CHILDREN'S HEALTH

Submitted in writing prior to
Hearing before the
Committee on Environment and Public Works
United States Senate

March 17, 2010

Thank you for the opportunity to submit testimony to this Committee. My name is Ted Schettler and I am Science Director of the Science and Environmental Health Network (SEHN). SEHN is a not-for-profit organization working in collaboration with environmental and public health groups, health professionals, legal scholars, ethicists, government officials, legislators, and others seeking to protect public health and the environment for this and future generations.

I am a physician and also have training in public health, toxicology, epidemiology, and environmental medicine. I practiced medicine for more than 30 years. I served on the U. S. Environmental Protection Agency's (EPA) Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) from 1996-1998 and the Endocrine Disruptor Methods Validation Subcommittee from 2001-2003. I also served on the National Academy of Sciences' committee on defining concerns associated with products of animal biotechnology.

The Vulnerability of Developing Children

From an extremely large body of scientific work we know that, compared to adults, developing children are uniquely susceptible to hazardous environmental exposures. Windows of vulnerability during *in utero* development, infancy, and childhood increase risks of some adverse health outcomes resulting from exposures, often with lifelong consequences. Among the better known examples, lead exposures that have minimal or no discernable impacts in adults can permanently alter brain development and function in a child. Similarly, fetal alcohol exposures can have lifelong impacts in children, while the same exposure in adults has only mild, transient effects.

Many of the reasons for this vulnerability are well understood and others are being worked out at the molecular, cellular, and tissue levels. During fetal, infant, and child development, cells rapidly divide, tissues and organs are formed, and signaling mechanisms, hormone levels, feedback loops, and their set points are established. Exposures to hazardous chemicals as well as other environmental influences may perturb these events through various mechanisms with long-term consequences.

It is also important to recognize the substantial and growing evidence showing that environmental exposures during development can increase the risk of chronic, degenerative diseases much later in life.[1] For example, life-long cumulative exposures to lead, including developmental exposures, increase the risk of cognitive decline and Parkinson's disease in people decades later. Animal studies show that early life exposure to certain pesticides seem to prime the brain, making it more susceptible to further exposures in adulthood, resulting in neurodegeneration in areas responsible for Parkinson's disease. Indeed, epidemiologic studies show an increased risk of Parkinson's disease in agricultural communities where pesticides are heavily used.[23] Thus, while protecting children, we are also lowering the risk of various diseases and disabilities much later in life.

Endocrine disruptors

One area of concern that I would like to highlight is the potential for some pesticides, metals, and various other industrial chemicals to disrupt the function of hormones and other chemical messengers that are vital to normal human development and function. These chemicals are known as endocrine disruptors.

An endocrine disruptor is "an exogenous agent or mixture of agents that interferes with or alters the synthesis, secretion, transport, metabolism, binding action, or elimination of hormones that are present in the body and are responsible for homeostasis, growth, neurological signaling, reproduction and developmental processes."[4] Endocrine disruptors interfere with the body's key signaling pathways and can cause harm, especially during fetal and early life development.

Endocrine disruptors gained increased public and scientific attention during the 1990s, although the capacity for certain industrial chemicals to mimic or otherwise interfere with hormone function was known at least as long ago as the 1930s. For example, in 1938, scientists showed that bisphenol A, a chemical used to make many consumer products today, has estrogen-like properties, although its molecular structure is quite different from naturally-occurring estrogen.[5] The use of this chemical is now so widespread that, according to the Centers for Disease Control and Prevention, 93% of all Americans have residues of bisphenol A in their urine.[6] Recent studies link bisphenol A levels to altered brain development, heart disease, and diabetes.[7] [8]

In the 1950s, 1960s, and early 1970s the potent synthetic estrogen, diethylstilbestrol was purposely given to many pregnant women with the unfounded promise that it would help to prevent miscarriages and promote healthier pregnancies. Tragically, fetal exposure to DES resulted in abnormalities of reproductive tract development in females and males and a sharply increased risk of reproductive tract cancers in women decades later.[9] [10] Thus, we learned through uncontrolled human experimentation that certain chemicals could profoundly alter development with consequences that were often not apparent at birth and might only become manifest decades later.

During the 1980s and 1990s exposures of wildlife to industrial chemicals and their health effects were increasingly reported in the scientific literature.[11] [12] Reproduction and development of birds, amphibians, reptiles, and mammals have been affected by exposure to endocrine disrupting chemicals.[13] Fish in numerous rivers, including the Potomac, have disrupted sexual development—specifically feminized male fish. When this finding was first noted in England in the 1990's,[14] it was considered unusual. It is now recognized as a widespread, pervasive phenomenon.

Based on findings in wildlife and laboratory animal studies, many scientists are concerned that in humans, the increasing incidence of cancer of the testis, prostate, and breast, birth defects of the male reproductive tract, lower sperm counts, behavioral disorders, diabetes, and a wide range of other abnormalities may result, at least in part, from exposures to endocrine disrupting chemicals.[15]

A recent report shedding new light on a puzzling observation that has baffled scientists for years is illustrative.[16] Many studies find a higher incidence of testicular cancer and male reproductive tract abnormalities in Danish men than in nearby Finland. Finnish boys have larger testes and higher sperm counts than Danish boys. Reasons for these differences have been unclear. Recently, scientists analyzed the breast milk of 68 women from the two countries for 121 different chemicals and found significantly higher levels in the milk of the Danish women. The chemicals tested for included flame retardants, pesticides, phthalates, polychlorinated biphenyls, dioxins, and furans. These chemicals are commonly identified in biomonitoring studies around the world, including in the US. Their concentration in breast milk is a good indicator of fetal exposures during pregnancy. Clearly, this kind of study cannot definitively establish a causal relationship between the different levels of these industrial chemicals in mothers in Denmark and Finland and the patterns of male reproductive tract abnormalities in the two countries. But a causal relationship is entirely plausible, based on what we know about the effects of many of these chemicals in laboratory animal studies. Current environmental exposures also include hundreds if not thousands of chemicals that were not tested for in this study that may also be part of the problem.

Because of growing concern about endocrine disrupting chemicals, in 1996 the EPA created the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) in response to a Congressional mandate in the Food Quality Protection Act and authorization in the Safe Drinking Water Act Amendments of 1996.

These laws specified that EPA:

> "...develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effect as the Administrator may designate."

The laws required EPA to develop a screening program by August 1998, to implement the program by August 1999, and to report on the program's progress by August 2000. Unfortunately, EPA is now about a decade behind.

I served on the EDSTAC. The committee included representatives from industry, government, environmental and public health groups, and academia. We were charged with developing consensus-based recommendations for a screening program that would provide EPA the necessary information to make regulatory decisions about endocrine effects of chemicals.

The committee delivered a final report by the statutory deadline of August 1998.[17] It included a groundbreaking priority setting, screening and testing approach that encompasses the universe of chemicals in use today, evaluates a range of human health and ecological effects, and recommends a feasible, health-protective, approach. The committee:

- recognized that problems with endocrine disruption go beyond estrogen, and also called for screening of chemicals for interference with male androgens and thyroid hormone.
- recommended the use of new technologies to rapidly pre-screen numerous chemicals to see if they interact with hormone receptors *in vitro* (in the "test-tube"). The committee recommended that this technology be used to rapidly evaluate the ten thousand most widely-used chemicals within one year.

- recommended a computer-based tracking system allowing information about health effects and exposure to be collected in one place to facilitate prioritization. That database didn't exist then, and it doesn't exist today.
- urged EPA to accept nominations from the public of chemicals or *chemical mixtures* for expedited testing. This would allow workers, or impacted communities to press for more information about chemicals to which they are exposed.

Unfortunately, EPA missed deadline after deadline and became bogged down in an endless set of validation exercises that remain unfinished. Many of the recommendations were discarded. Finally, a decade late, EPA implemented an extremely scaled down version of the program when it issued the first test orders in October, 2009. Only 67 chemicals are on the list for this first round of screening – mostly pesticides, including a number of chemicals that are already well-known endocrine disruptors.[18] Meanwhile tens of thousands of chemicals in consumer products, food, water, and air have not been tested for endocrine disrupting properties.

In 2009 the Endocrine Society evaluated the science on endocrine disruptors and concluded:

> "The evidence for adverse reproductive outcomes (infertility, cancers, malformations) from exposure to endocrine disrupting chemicals is strong, and there is mounting evidence for effects on other endocrine systems, including thyroid, neuroendocrine, obesity and metabolism, and insulin and glucose homeostasis."[19]

The Endocrine Society is the premier professional organization devoted to research on hormones and the clinical practice of endocrinology. It is comprised of over 14,000 research scientists and physicians from over 100 countries. This statement has since been endorsed by the American Medical Association, which is joining the Endocrine Society in calling for decreased public exposure to endocrine disrupting chemicals. The American Chemical Society just issued a similar statement with additional recommendations for: "More rapid advancement of the congressionally-mandated effort by the EPA, called the Endocrine Disruptor Screening Program (EDSP)."[20]

As a result of EPA's failure to implement a strong endocrine disruptor screening program, the *Endocrine Disruption Prevention Act* was introduced in Congress in 2009. This act would authorize a new research program at the National Institute of Environmental Health Sciences (NIEHS) to identify endocrine disrupting chemicals, using the most current science. It would establish an independent panel of scientists to oversee research and develop a prioritized list of chemicals for investigation. If the panel determined that a chemical presented endocrine-disrupting concerns, it would compel the federal agencies with established regulatory authority to report to Congress and propose next steps within six months. NIEHS has the capacity to carry out such a research program if provided with appropriate resources. But EPA remains the regulatory authority responsible for protecting children from environmental threats.

I have focused here on endocrine disrupting chemicals, but my concerns about human exposures to industrial chemicals are not limited to those with endocrine disrupting properties. Well-known flaws in the Toxic Substances Control Act (TSCA) have allowed tens of thousands of untested industrial chemicals to stay on the market and new ones brought to market with limited or no toxicity information. These include chemicals to which workers and people in the general population, including pregnant women and children, are regularly exposed.

The EPA Office of the Inspector General's (OIG) report, released in February, 2010, and previous GAO reports clearly describe these problems.[21] [22] Not only are basic safety data lacking, but whatever limited information is submitted to the agency is frequently accompanied by requests to protect it from public disclosure. The OIG report concludes that the agency's process is "predisposed to protect industry information rather than to provide public access to health and safety studies." Physicians and other health care professionals do not have access to the data they need in order to appropriately advise patients, and workers and communities remain ignorant of the potential hazards of the chemicals to which they may be exposed.

Meaningful TSCA reform is essential in order to protect developing children and people of all ages from the impacts of exposure to hazardous chemicals in consumer products, food, water, and air.

The impacts of industrial chemicals, including pesticides, on brain development and function

Another area of concern to bring to your attention is the failure of EPA to require adequate evaluation of the impacts of industrial chemicals, including pesticides, on brain development and function in children. Ample scientific evidence confirms the unique susceptibility of the developing brain to chemical exposures that can disrupt one or more of a number of biologic processes that must proceed in an orderly fashion as brain architecture and chemistry are established throughout pregnancy, infancy, and childhood.

Lead, mercury, polychlorinated biphenyls (PCBs), arsenic, ethyl alcohol, and toluene are recognized causes of neurodevelopmental disorders.[23] A large body of experimental and human epidemiologic evidence shows diverse, long-lasting impacts of these substances on the ability of children to learn, remember, pay attention, and behave appropriately. The effects can occur after relatively low-level exposures that have no discernable effects in adults.

Policies that reduce exposures to these substances have been successful. For example, the removal of lead from gasoline resulted in a sharp decline in average blood levels in children throughout the US. Even so, the economic consequences of lower IQ resulting from lead levels in children in the US today are conservatively estimated to be in excess of $40 billion annually.[24] That figure does not take into account costs to society incurred by responding to special educational needs and disruptive or criminal behavior.

Unfortunately, these well-studied substances are the exception. The large majority of industrial chemicals have never been evaluated for their potential impact on the developing brain of children. This is true even for those chemicals known to be toxic to the nervous system more generally.

Pesticides and organophosphates

Under the Federal Insecticide, Fungicide, and Rodenticide Act, the EPA has the authority to require pesticide registrants to provide data about the impacts of their chemicals on the developing brain. But these data are not part of the core requirement, and the agency may decide on a case-by-case basis whether to require their submission. Historically, the EPA has always been reluctant to exercise this authority, even when a food-use pesticide was known to have nervous system toxicity as the mechanism whereby it killed pests.

Organophosphates are a group of pesticides that are notorious nervous system toxicants. They disrupt nerve impulse transmission and can cause a plethora of symptoms. In the 1990s and early 2000s a delayed, slow trickle of developmental neurotoxicity data on various organophosphates was delivered to EPA by registrants after a data call-in. These data finally led to some restrictions, including a phase out of chlorpyrifos-containing products for home and garden use. Chlorpyrifos is among the organophosphate pesticides known to adversely impact the developing brain of children as well as laboratory animals.[25] But chlorpyrifos remains in widespread agricultural use in the US today.[26] About 8 million pounds are applied to US crops annually. Children in farming communities are regularly exposed to this and other organophosphate neurotoxins.[27] It is difficult to imagine the justification for continued use of chlorpyrifos in agriculture.

Methyl iodide

Recently, the EPA considered a registrant's application for the agricultural use of the fumigant methyl iodide (MeI). This chemical should have waved red flags within EPA, demanding neurodevelopmental toxicity testing before registration. Yet, EPA failed to require it and registered the chemical for use without knowing what it might do to the developing brain of a fetus, infant, or child.

MeI was developed as a substitute for methyl bromide, a fumigant that is supposed to be phased out under the Montreal Protocol because it depletes stratospheric ozone. MeI is an extremely toxic chemical that must be handled with extraordinary care in the laboratory setting. It is damaging to DNA, causing mutations, and is listed on the California Proposition 65 list as "known to the State of California to cause cancer." But, here I want to focus on impacts of MeI on the developing brain.

Methyl iodide is highly likely to be a developmental neurotoxicant, with long-lasting impacts on the brain of fetuses, infants, and young children at levels of exposure lower than those that cause damage to the adult brain. This concern is based on several lines of evidence:

Methyl iodide is a documented neurotoxicant. The Material Safety Data Sheet from Mallinkrodt-Baker Inc. (italics added) states[28] "DANGER! MAY BE FATAL IF SWALLOWED, INHALED OR ABSORBED THROUGH SKIN. *AFFECTS CENTRAL NERVOUS SYSTEM.* CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT.

U.S. EPA's own risk assessment begins the discussion of MeI (here called iodomethane) toxicity with the following statement (italics added):

> "The pattern of toxicity attributed to iodomethane exposure *via* the inhalation route includes developmental toxicity (manifested as fetal losses and decreased live births), histopathology findings (respiratory tract lesions and salivary gland squamous cell metaplasia), thyroid toxicity, *neurotoxicity* and generalized systemic toxic effects (body weight and body weight gain decreases). The critical effects of iodomethane exposure via the inhalation route are the fetal losses observed in two developmental toxicity studies in rabbits, the histopathological lesions reported in three studies, and *the neurotoxic effects (clonic convulsions, decreased body temperature and motor activity)* seen in the acute neurotoxicity study in rats." (U.S. EPA, Human Health Risk Assessment: Iodomethane, page 4)
>
> and
>
> "**Acute inhalation:** Three critical endpoints have been identified for this risk assessment: nasal histopathology in the subchronic inhalation toxicity study in rats, the fetal losses in the developmental toxicity study in rabbits, and *neurotoxicity in rats*." (U.S. EPA, Human Health Risk Assessment: Iodomethane, page 4)
>
> and
>
> "*In regards to the potential role of iodomethane as a neurotoxicant, the inhalation acute neurotoxicity study in rats revealed that iodomethane exposure elicited clonic convulsions (repetitive mouth and jaw movement), a 2-3°C decrease in body temperature, and an 80% decrease in motor activity in the absence of neuropathology*." (U.S. EPA, Human Health Risk Assessment: Iodomethane, page 13)

Reports of human exposure to MeI are published in the medical literature. Individuals who have been acutely exposed to sufficient levels of MeI, usually accidentally in an occupational setting, may develop "symptoms of irritability, headache diplopia, nystagmus, lethargy, somnolence, slurred speech, ataxia, dysmetria, and visual disturbances. Parkinsonism and cerebellar neurologic dysfunction are manifest. These symptoms may progress to paralysis, convulsions, coma, and death. If recovery occurs, the acute neurologic symptoms may recede over several weeks, giving way to late neuropsychiatric sequelae such as behavioral disturbances, and cognitive deficits, psychoses, and emotional lability." [29] [30]

The mechanism(s) by which MeI exerts its neurotoxic effects are not completely understood. However, it is clear that glutathione (GSH) depletion is an important contributor in the causal pathway leading to neurotoxicity. [31] Glutathione is a naturally-occurring antioxidant that enables the body to cope with toxic substances that cause oxidative stress. Several studies conclude that glutathione depletion alone leads to neurotoxicity. [32] [33] In these studies, depletion of glutathione prior to methyl iodide exposure enhanced neural cell damage and supplementation of glutathione prior to exposure was protective. The authors conclude that oxidative stress and associated mitochondrial damage are critical components of the neurotoxicity of MeI.

With the above in mind, it is worth noting that fetuses and infants normally have lower levels of glutathione in their tissues than young adults. [34] [35] [36] [37] (Glutathione levels also decline in older people. That is, general anti-oxidant capacity is diminished in the very young and the aged.) Children's exposures can also be predicted to be higher than adult's per pound of body weight because of higher respiration rates of the child relative to an adult. Lower baseline levels of glutathione would be anticipated to increase susceptibility to a neurotoxicant like iodomethane whose mechanism of action depends, at least in part, on glutathione depletion. For that reason alone, it can be predicted that the developing brain is more vulnerable to MeI neurotoxicity than the fully developed adult brain. Beyond that, however, impacts of oxidative stress differ in the developing brain because of unique developmental events without counterparts in the adult.[38] Moreover, the results of impairment of developmental processes in the brain are typically long-lasting and often irreversible.

Despite all this, the EPA did not request a developmental neurotoxicity test for MeI, indicating in its response to 54 scientists who expressed their concerns that:

> "In the case of iodomethane, the thyroid-related effects are more sensitive (i.e., occur at lower exposure levels) than the neurotoxic effects seen in the data. Moreover, given the pivotal role that thyroid hormones play in the development of the nervous system, the Agency concluded that by regulating at an exposure level that would prevent perturbations in the thyroid hormone balance it would in turn be protective of potential effects on the developing nervous system. As a result, the Agency did not require the DNT since the point of departure use in the risk assessment is based on a more sensitive endpoint." (October 5, 2007 letter from Jim Gulliford to Professor Robert Bergman; UC Berkeley)

This rationale suggests that the agency believes either that: 1) thyroid toxicity is the only pathway available for developmental neurotoxicity for this chemical and if fetal thyroid toxicity is prevented, any and all developmental neurotoxicity will be prevented, or 2) neurodevelopmental impairment due to oxidative stress is a less sensitive endpoint than impairment due to thyroid hormone changes. Unfortunately, there is no basis for either of these conclusions.

The toxicological literature documents a variety of mechanisms by which neurodevelopmental toxicants may impart damage to the developing brain, most of them unrelated to the thyroid gland. (they include, but are not limited to, oxidative stress, nitrative stress, alteration in neurotransmitter levels, alterations of cell adhesion molecules, alterations in DNA synthesis) Some developmental neurotoxicants have multiple mechanisms of action. In a meeting report on alternatives to animal developmental neurotoxicity testing, the authors concluded:[39]

> ". . . because of the complexity of the developing brain, it is likely that there are many molecular mechanisms of developmental neurotoxicity, a conclusion borne out by mechanistic studies of neurodevelopmental diseases. However, significant advances in our understanding of the cellular and molecular mechanisms of neurodevelopment over the past 10 years have identified and characterized key cellular events that are critical to the formation of a functional nervous system. These include neural induction, precursor cell proliferation, pattern formation, cell migration, neuronal and glial differentiation, formation of axons and dendrites, axonal guidance and target recognition, cell survival and apoptosis, synapse formation and pruning, and neurotransmitter specification."

Recent work on the developmental neurotoxicity of organophosphate pesticides demonstrates that chlorpyrifos interferes with DNA synthesis in neuronal cells in the developing brain, leading to a number of adverse impacts.[40]

> "In animal studies or *in vitro* models of neurodevelopment, chlorpyrifos has direct and indirect effects on neural cell replication and differentiation, resulting in immediate and delayed-onset changes in synaptogenesis, neurotransmitter release, expression of neurotransmitter receptors, and intracellular signaling over and above the consequence of cholinesterase inhibition."

Moreover, Slotkin et al. have shown that impacts on DNA synthesis occur at levels of exposure that are insufficient to significantly alter neurotransmitter levels. Oxidative stress plays a role in these outcomes.[41] The point here is not to suggest that MeI should be compared to organophosphates. Rather, the point is that multiple mechanisms of developmental neurotoxicity have been documented, and protecting against one does not necessarily protect against others.

Nevertheless, in October, 2007 the EPA approved a time-limited conditional registration of MeI and extended that registration in 2008, without requiring neurodevelopmental toxicity testing. Subsequently, while considering registering MeI for use in California, the Department of Pesticide Regulation carried out its own risk assessment and sent it out for external review by a Scientific Review Committee (SRC). In its final report, when describing their process and conclusions, the SRC said:[42]

> "The comments provided by the farm workers made a particular impression on the SRC by providing a real world perspective specifically based on their experience with the analogous toxin, methyl bromide. From this testimony (predominantly from a group organized by growers), it was abundantly clear that respiratory protection, despite strict regulations on paper, is commonly inappropriate, inadequate, or inaccessible.
>
> An equally important element in our review was the data that we would have wished to assess but that was insufficient or non-existent altogether. This palpable lack of sufficient data raises serious doubts about the adequacy of any risk assessment to fully estimate the risks that would be associated with the introduction of methyl iodide into the general environment.
>
> The lacunae in our knowledge about methyl iodide are particularly wide and deep in relation to key aspects of its potential toxicity such as neuro- and other developmental effects, neuro-toxicity beyond the development stage (in particular, following chronic exposure), and mechanisms of carcinogenicity."

This is a description of the existing data gaps pertaining to this dangerous, highly toxic chemical. EPA had the authority to require neurodevelopmental testing before registration but didn't, despite concerns voiced by numerous scientists. EPA's rationale simply does not stand up to scrutiny.

Recommendations:

EPA should:

1. Move more quickly to implement the Endocrine Disruptor Screening Program for chemicals in consumer products, air, food, and water, using current, up-to-date scientific methods. Evaluation should include commonly encountered mixtures as identified in environmental media (air, water, food) and biomonitoring studies. If NIEHS becomes the institution in which the endocrine disrupting properties of chemicals are evaluated, EPA must then promptly respond to the findings with health protective interventions.
2. Require developmental neurotoxicity testing of MeI and suspend its registration until data gaps are filled and risks have been re-evaluated.
3. Routinely require neurodevelopmental toxicity testing of pesticides proposed for registration or continued use when they are known or suspected to be toxic to the nervous system.

Congress should pass comprehensive chemical regulatory policy reform. Effective reform should:

- **Immediately Initiate Action on the Worst Chemicals**: Persistent, bioaccumulative toxicants (PBTs) are uniquely hazardous. Any such chemical to which people could be exposed should be phased out of commerce.
- **Require Basic Information for All Chemicals**: Manufacturers should be required to provide basic information on the health hazards associated with their chemicals, how they are used, and the ways that the public or workers could be exposed.
- **Protect the Most Vulnerable:** Chemicals should be assessed against a health standard that explicitly requires protection of the most vulnerable subpopulations. That population is likely to include children, but it could also be workers, pregnant women, or another vulnerable group.
- **Use the Best Science and Methods**: The National Academy of Sciences' recommendations for reframing risk assessment at the EPA should be adopted. Regulators should expand development and use of information gleaned from "biomonitoring" for setting priorities.
- **Hold Industry Responsible for Demonstrating Chemical Safety**: Chemical manufacturers should be responsible for evaluating and demonstrating the safety of their products.
- **Ensure Environmental Justice**: Effective reform should contribute substantially to reducing the disproportionate burden of toxic chemical exposure placed on people of color, low-income people, and indigenous communities.
- **Enhance Government Coordination**: The EPA should work effectively with other agencies such as the Food and Drug Administration that have jurisdiction over some chemical exposures. The ability of the states to enact stricter chemical policies should be maintained and state/federal cooperation on chemical safety encouraged.
- **Promote Safer Alternatives**: There should be national support for basic and applied research into green chemistry and engineering, and policies should favor chemicals and products that are benign over those that are hazardous.
- **Ensure the Right to Know**: The public, workers, and the marketplace should have full access to chemical safety data and information about the way in which government safety decisions are made.

Congress should also adopt legislation establishing the Endocrine Disruption Prevention Program so that 1) environmental chemicals can be screened for endocrine disrupting properties using the most current science in a timely manner and 2) regulatory agencies are obligated to take action to protect public health based on the best available science.

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Senator KLOBUCHAR. Thank you very much. And thank you for sort of bringing this down to the real world level and the kids that you deal with in your work. I was listening to this thinking of— I had not related this, but of my own experience when my daughter was born. She could not swallow for a year and a half, and no one could figure out what was wrong. We still do not know what was wrong. She somehow snapped out of it after being on a feeding tube, and I spent many weeks in the neonatology unit and things like that.

When I look back on that time now, because she is an amazing kid and she has no permanent thing, there was nothing genetic, I always think about time is a gift. One, it gave me a sense of what parents with kids with disabilities go through. But two, it made me always wonder was I exposed to something when I was pregnant? What happened? How did this happen? And how did she suddenly snap out of it when it was not a permanent problem?

I know a lot of parents dealing with kids with autism and other things that just daily wonder the same thing as we see these sudden increases in certain diseases and do not know what they are. That is one of the things that drive so many families to want to see that research and just feeling so alone out there, you know, surfing the Internet, coming up with theories that make no sense because they read them on a blog, when we should be looking at these scientifically, and we should be getting the data collected.

So, I want to tell you how I know that I and so many families share that frustration that we are not getting the data, Dr. Schettler, that you are talking about.

So my question, first of all, is how do you think, in the ideal world, this Interagency Task Force could work to try to better share things? And what do you think, as we look at, you know, difficult budget times for Government, what do you think the most cost effective way and where should our focus really be as we look at all the myriad of potential problems we have here?

I know those are two big questions. The first would be how the Interagency Task Force could be better coordinated, and I guess the second would be how we could do this most cost efficiently and what our focus should be.

I guess, Dr. Bearer, that I will begin with you because I mentioned you. You can all three answer it.

Dr. BEARER. Thank you. I see the Interagency Task Force as being able to link across agencies various pockets of pediatric environmental health. For example the biomonitoring programs at CDC to be linked to EPA's list of priorities for chemicals that need to be studied, to the NIH where research dollars need to be spent in order to assess the toxicity of the chemicals.

I also see it as a clearinghouse for research and initiatives of what is actually going on right now. There is no place where you can go to find out what research is actually being done. And I see the Interagency Task Force as being important in collecting and organizing and making publicly available what research is actually happening.

Senator KLOBUCHAR. Thank you.

Dr. Solomon.

Dr. SOLOMON. In addition to coordinating with agencies such as CDC for chemicals that are in food contact materials and in consumer products, such as known endocrine disrupters like bisphenol A and phthalates, we are finding that FDA and CPSC have very major regulatory roles and yet often do not have the same toxicologic approach or expertise in those chemical areas as EPA.

And it is really important also to have consistency. We saw this as a problem when EPA and FDA were publicly disagreeing a number of years ago about levels of mercury that are safe for women of reproductive age, and very recently FDA, EPA and NIEHS sort of came together around bisphenol A, and they are trying to come to a common ground. So, it is very, very important to avoid conflicting standards or conflicting messages to the public as well.

But I also think in terms of priorities, you know, all three of us mentioned chemical policy reform. It really is a huge, huge issue——

Senator KLOBUCHAR. You are talking about TSCA?

Dr. SOLOMON. Yes, TSCA is the main issue area where we are dealing with both enormous data gaps that impair all of us as physicians from being able to provide information to patients and communities and also the problem that EPA does not have the authority it needs to take regulatory action even when there is evidence showing harm to developing organisms and children.

Senator KLOBUCHAR. When you think about all the new products and changes in our society and the fact that it has not been updated for so long, it clearly cries out for some changes.

Dr. SOLOMON. Exactly. The science has moved forward; there is a lot of information from the National Academy of Sciences to go with, and that really is something that needs action soon.

Senator KLOBUCHAR. OK.

Dr. Schettler.

Dr. SCHETTLER. I would agree with the need for coordination across the agencies and do not have more to add to that. It is important that we not sort of Balkanize this and fail to look at it comprehensively.

With respect to the second question, the issue of cost effectiveness, I would agree first of all with the importance of TSCA reform, and some of the elements of that have to include that chemical manufacturers need to be responsible for evaluating the safety of their products. I mean, this should not fall on the public to do that after the fact. So, it should be, you know, pre-market testing is required. If you are going to stay on the market, we need safety data.

But I also would like to add a little more to this idea of cost and benefits which came up in the first panel. We know that a lot of the childhood conditions that we are concerned about today are setting the stage for an overwhelming wave of disease and disability that is coming down, that is going to overwhelm us in the next several decades.

As was pointed out in the first panel, childhood obesity itself is a risk factor for diabetes, cardiovascular disease, cognitive decline, dementia and Alzheimer's disease. And I am not certain what we are going to do about this. And at a time when we are talking about healthcare reform in this country we should be really looking at what is coming as we try to figure out primary preventive strategies to try to prevent this flood of chronic disease that is coming along.

So when we are doing our cost-benefit analysis, let us look at the whole picture, and let us look at it over time and see how we are going to be dealing with that decades from now as well as in the shorter term. Thank you.

Senator KLOBUCHAR. Very good. Thank you.

I just want to ask a few specific questions with some work that I am doing, legislation that we are working on. I mentioned formaldehyde. And there is a huge problem of some of these wood products coming over, primarily from overseas, because our own timber industry has agreed to some standards voluntarily. But yet we are seeing—there is the whole trailer issue down in Katrina and those things of formaldehyde in these woods.

That is why Senator Crapo and I have a bill that basically follows the California Standards, Dr. Solomon. And I can tell you it was quite interesting to stand with our timber industry in Minnesota at a Home Depot where we were supporting this bill to take up the California standards nationally and having the industry people talking about how they wanted the California standards. You can bring that home with you.

But because of the fact that these wood products are coming in with formaldehyde, and they are unfairly competing with our own American timber, that is actually in wood products that are actually abiding by these higher standards. I just wondered if any of you—and I do not expect all of you could comment on the formaldehyde issue with kids.

Dr. SOLOMON. I am happy to comment because I have been in numerous of those FEMA trailers. I spent a lot of time in New Orleans after Katrina. I talked with families who lived in FEMA trailers for months or even years and heard first-hand from them about the symptoms that they were suffering from, ranging from increased rates of asthma to just constant nagging irritation of the upper airways and constant headaches. This would have been so preventable, so avoidable.

I think that there is a broad concern about voluntary agreements that is raised by this issue because a voluntary agreement is good as long as everyone abides by it. But in this age of global commerce it is very hard to get the entire industry—especially internationally—on board.

We are seeing that more recently with the flame retardants where there have been voluntary agreements with U.S. manufacturers of these polybrominated diphenylether flame retardants, PBDEs, to take them off the market. But I personally am very concerned that we are going to still be seeing them in imports from other countries. So this is why Congress needs to take action and why EPA also needs to take regulatory action and not count on voluntary agreements to protect the public.

Senator KLOBUCHAR. Right.

Cadmium in jewelry, speaking of imports, anyone have any familiarity with that the effect on kids? No one? OK. That is all right. I think I have asked the EPA about this in the past, so I appreciate that.

Other things that we have been working on are radon and the effect on children of that. We are putting together a bill in that area. And then, as you know, Senator Boxer has been a leader on perchlorate monitoring and the Right to Know Act and has done a lot in that area.

So, there are a lot of specific things that we are working on that I cannot help but think cry out for action about having this Interagency Task Force where we are drawing these resources together, as you say, for research, which will really help us in Congress so that when we move ahead in one area, we are not just doing one little thing, maybe we should be doing three things at the same time. I think it will be very helpful if we could get that Task Force going.

Is there anything anyone else would like to add today?

Dr. SCHETTLER. I would like to add one more comment. Thank you for the opportunity.

As I listened to the discussion about perchlorate and about formaldehyde and air pollution I think it is important for us to keep in mind that we are not exposed to these various contaminants one at a time, but we are exposed to mixtures. And it occurs in a social and an economic environment which may cause either more or less vulnerability. This is all fairly well outlined in the National Academy of Sciences' report on science and decisions. But these are very real issues.

So, people are not just exposed to perchlorate. In farming communities, for example, there is going to be nitrate in the water at the same time. There may be women who have inadequate iodine intake in their diet. Thirty percent of women in the United States are estimated to have suboptimal intakes of dietary iodine, making them more susceptible to the effects of perchlorate and nitrate in terms of being able to produce enough thyroid hormone for their baby to develop in utero. So, we need to think about these things collectively.

Similarly, children who are exposed to formaldehyde and air pollution who also happen to be living in suboptimal socioeconomic environments are more likely to develop asthma as a result of those exposures because the social environment creates vulnerability.

So, these do need to be looked at through sort of this interagency comprehensive approach that will recognize that there are vulnerable populations of people among the general population who do need to be protected.

Thank you.

Senator KLOBUCHAR. All right. Thank you.

Dr. Solomon. We usually do not do this at the end, but you know, you are up here, and it is just me, so add your final comments here.

Dr. SOLOMON. Thank you for the opportunity for a final comment.

I have served on a number of EPA advisory committees over the years, including the Drinking Water Committee, and have been frustrated at how long it takes from the time when there is enough scientific information to take action to when action actually occurs. And perchlorate is an excellent example of a chemical that has been under study for well over a decade and where there is extremely strong information about exactly what it does in the human body and enough data, even in humans, on which to take action. And yet this chemical has not been regulated yet.

I have seen the same thing with numerous industrial chemicals. It was a decade ago that the Science Advisory Board reviewed the trichloroethylene risk assessment and recommended that it be finalized as soon as possible. But a decade has passed, and it is now undergoing another round of review.

That is the type of pattern that tends to occur, and one of the things that will be important with TSCA reform will be to get out of that endless loop of repetitive, interminable risk assessments. We certainly also saw it with dioxin, another ongoing example.

So, EPA really does need not only the authority but in fact the responsibility to take rapid action when there is information, scientific evidence, showing harm to children's health.

Senator KLOBUCHAR. OK. Thank you.

Dr. BEARER. I would really like to say that I think the National Children's Study should go forward to generate some of this data because not only has Dr. Schettler noted that we are exposed to mixtures, but we are exposed over time. And with children that can be important for setting them up to future vulnerability following a previous chemical exposure.

So, until we understand this complex play of determinants on our health but occurring over time in our children I do not think we will have a good idea of what is actually impacting our health.

Senator KLOBUCHAR. OK.

Well thank you, all of you. This has been very enlightening, and I think you have seen a number of Senators that came by today who are similarly devoted to moving forward on this. I know the EPA is, and I appreciate the GAO work as well in looking at this and stepping back and looking at how we can do better.

I wanted to note that Senator Boxer, I think she talked to me about this hearing five times in the last 24 hours. She really had wanted to be here and cares a lot about this. She has been a true leader on this issue. She even caught me in the hallway and said you are going to be 5 minutes late. She would be here, but as you know there is a lot going on right now in the U.S. Senate, and so she was needed elsewhere to work on some very time sensitive issues. I know she wanted to be specifically here to greet you, Dr. Solomon.

I am going to put her statement on the record and also the GAO report on Environmental Threats to Children, as well as the EPA's 1996 National Agenda on Children's Health. So, without objection, those things will be included in the record.

And we look forward to working with all of you this important issue as we go ahead.

Thank you very much, and the hearing is adjourned.

[Whereupon, at 12:05 p.m. the full Committee was adjourned.]

[Additional statements submitted for the record follow:]

STATEMENT OF HON. BARBARA BOXER, U.S. SENATOR FROM THE STATE OF CALIFORNIA

Children are more vulnerable to toxic pollution than adults. Their bodies are developing rapidly—including their brains, hearts and lungs, their nervous and immune systems—so exposures to toxic chemicals at critical times in their development can have lifelong impacts.

That's why I wrote the law that ensures that the EPA takes children and other vulnerable populations, such as pregnant women and the elderly, into account when setting drinking water standards, not just healthy adult men.

And that is why I asked the Government Accountability Office (GAO) to investigate the EPA's role in protecting children's health and to give me a report card on how the Federal Government is doing in keeping our children safe from environmental dangers.

As the GAO has said in its report, "Children face disproportionate health risks from environmental contaminants such as pollution in air, lead paint in homes, pesticide residues on food, and treatment resistant microbes in drinking water. Such hazards contribute to asthma, cancer, neurodevelopmental disorders, and other diseases, and many of the Nation's 74 million children are exposed to them daily."

Senator Klobuchar joined me in this request as Chair of this Committee's Subcommittee on Children's Health. Today we are releasing GAO's final report, the culmination of an in-depth 2-year investigation. Based on GAO's report I am very concerned that EPA has not followed through on its initial commitment in the late 1990s to make children a priority with the creation of the Office of Children's Health and other steps designed to put kids first.

The GAO report paints a clear picture:

First, the GAO found that EPA has not focused attention on children's health in agency-wide priorities, strategies, and rulemakings.

GAO also found that EPA has not fully utilized its Office of Children's Health Protection and other child-focused resources.

At the same time, GAO concluded that opportunities exist for EPA to lead and coordinate national efforts to protect children from environmental threats. The current Administration has begun the task of returning the focus to children as a central mission of the agency. I applaud these efforts, but there is much more work to do.

I am working on a bill with Senator Klobuchar that would authorize an interagency task force geared toward protecting children's health from environmental threats. This task force was originally put in place by President Clinton in an Executive Order, but the task force lapsed, and we want to make sure that the work of this important group is made permanent.

I am also working with Senator Bill Nelson, who is here to testify today, on legislation to strengthen the EPA role in investigating cancer, birth defects, and other disease clusters that may be associated with environmental toxins.

Communities that experience unusual increases in birth defects, cancers and other diseases, especially in children, should get more help from the Federal Government, including EPA, in getting to the root of the problem. In my home State we have a community in Kettleman City that is working with the State of California to investigate the reason for the level of birth defects, and Senator Nelson will talk about a community in Florida and their efforts to determine the cause of the childhood brain cancers being experienced there. Senator Nelson and I would like to make sure these communities and others like them around the country can get the help they need so they can get answers quickly.

The goal of this oversight hearing today, as well as the legislative efforts we have underway, is very straightforward. Protecting children's health must be central to EPA's mission across the board, and the Agency must specifically remedy the deficiencies identified by the GAO when it comes to this critical issue. Our legislative efforts are designed to accomplish the same thing—to ensure the health and safety of children in communities across the country.

STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

I am a father and grandfather, so obviously protecting the health of children, born and unborn, is a personal priority. The best way to protect children's health is to use the best available science to properly assess risk. In some cases, children can be more susceptible, in other cases less susceptible, and in many cases equally susceptible to environmental exposures when compared to adults. On a body weight basis children can have greater exposure than adults, but not always. EPA takes these susceptibility differentials into account when assessing potential risks to children.

This follow up GAO investigation into efforts to protect children's health suggests to us, among other things, that the Agency has not fully used the Office of Children's Health Protection and has not prioritized children's health considerations in light of advisory recommendations.

However, what the report does not fully address is the fact that EPA must always balance recommendations on children's health with objective scientific standards, legal requirements, and practical realities. For instance we have been told that EPA should incorporate more of the recommendations of children's health advisory groups into Agency actions. But advisory groups do not have to base their recommendations on risk: they can base their opinion on the use of precaution. They do not have to balance economic impacts and resource limitations: Federal agencies do. And advisory groups almost never address whether the Federal Government should be or actually is authorized to regulate all issues suggested by their recommendations.

So, while EPA always takes advisory recommendations very seriously the Agency must independently review advisory findings and balance these opinions with the other factors that direct rulemaking and guide policy management.

Elements of GAO's report are instructive, and I look forward to hearing more. I especially agree with the report's favorable view of the National Children's Study. The National Children's Study will fortify the Government's commitment to the health and well-being of children—bringing together the top experts on children's health and the environment. The Study is the largest long-term study of environmental and genetic influences on children's health ever conducted in the United States. It will follow 100,000 children from before birth to age 21. Researchers will better understand how children's interactions with their environments affect their health and development.

But in contrast to what some of the witnesses will say today I do not believe that EPA needs additional congressional authority to specifically protect children's health. Rather I believe that EPA has the existing authority and processes in place to build upon ongoing Federal efforts to properly protect children's health. That said, I look forward to hearing your perspectives and welcome you to the Committee.

STATEMENT OF HON. MAX BAUCUS, U.S. SENATOR FROM THE STATE OF MONTANA

Madam Chairman, I want to take a few moments to talk about the health of the children of Libby, Montana, and to engage EPA officials today on this important topic. Libby is a beautiful little town in northwestern Montana. Libby is also a place where EPA has found asbestos contamination so pervasive—and the conditions so severe—that it warranted the declaration of a "public health emergency." The type of asbestos in Libby known as tremolite is particularly deadly. Tremolite fibers quickly find their way into victims' lungs and stay there. It's like a time bomb waiting to strike.

The effect of asbestos poisoning on Libby residents has been severe. Hundreds of people have grown sick and died due to the pervasive presence of asbestos spewed from the vermiculite mining and milling operations of W.R. Grace. Today we know that 291 people have died in Libby from asbestos exposure. That's 291 deaths in a community of just over 2,600 people. Lincoln County, Montana, home to Libby, has the highest age adjusted death rate due to asbestosis in the entire Nation.

I am in regular contact with the victims. Recently, I was written by a 55-year-old Libby resident, sick from asbestosis, with one concern—the long-term health of his grandchild:

"[A]t 55 and dying, I have been blessed, with a grandson, just 10 months old . . . I never knew I could love so much especially when I know my time is short. My grandson is the lifeline that is left from three generations of life/blood line that moved to a place so beautiful and God Given that no one would have guessed the monster that lie silent in the air and water and soil and lands in the lungs of all who breathe . . . what I take with me is knowing in my heart that Libby, Montana, killed my parents and killed me and killed my children. Libby will not kill my grandson."

We cannot allow this story to repeat itself. We cannot allow today's children to be told years from now, as this Libby resident was told, that their life is over. The asbestos in Libby has exacted an immeasurable toll on the parents of this generation. We cannot allow this to continue in our grandchildren.

So, as the current generation of Libby residents—through no fault of their own—suffers the horrible effects of this deadly poison, I am continuing my long standing efforts to be sure that EPA is taking every step possible to ensure that the clean up of Libby moves forward expeditiously and is based on accurate risk assessments for the unique type of asbestos in Libby. Today my question is—is EPA doing enough to ensure that the children in Libby, Montana, are protected from asbestos exposure? It would be unforgivable and tragic to create another generation of victims in Libby by failing to take every imaginable step to prevent their exposure to this known asbestos contamination.

The long-term health of the children of Libby should be our focus. We should act with an abundance of caution when making decisions that impact them. But ensuring their protection is not a one size fits all proposition. The existing EPA risk assessment procedures and existing science may not be adequate to address the special impacts of childhood exposures to asbestos. The multiple exposure pathways and the long-term consequences of cumulative exposures may need special focused attention. The comparisons of existing data on childhood exposures at other Superfund sites may not be applicable to the Libby. It is critical that the latest advancements in science, law and policy of children's health are integrated into the clean up decisions that directly impact the Libby community. EPA should redouble its efforts to address these special circumstances.

Today's GAO report identifies opportunities for greater focus, direction, and high level commitment to children's health at EPA. The report is critical of EPA's failure to institutionalize children's health issues into the overall activities of the Agency. However the report does identify the potential to start to get things right with the appointment of a permanent, stable and long-term office Director.

Therefore, today, the people of Libby want EPA's assurance that we are doing everything we can to protect the children of Libby. The people of Libby want EPA's assurance that the schools and playgrounds that we send our children to every day are safe. The people of Libby want EPA's assurance that its clean up assumptions and its policy of "allowable" and "acceptable" childhood exposure to asbestos will not create another generation of victims at Libby.

This assurance cannot come only from the clean up managers at EPA. It needs to come from the person in the Agency whose job it is to be the advocate for children's health—that is you, Mr. Grevatt.

I am asking you to join me in keeping the promise and fulfilling the long-term commitment that we have made to the people and particularly the children of Libby, Montana. We owe it to the next generation.

I thank our distinguished panel, and I look forward to your response.

[The referenced information follows:]

United States
Environmental Protection
Agency

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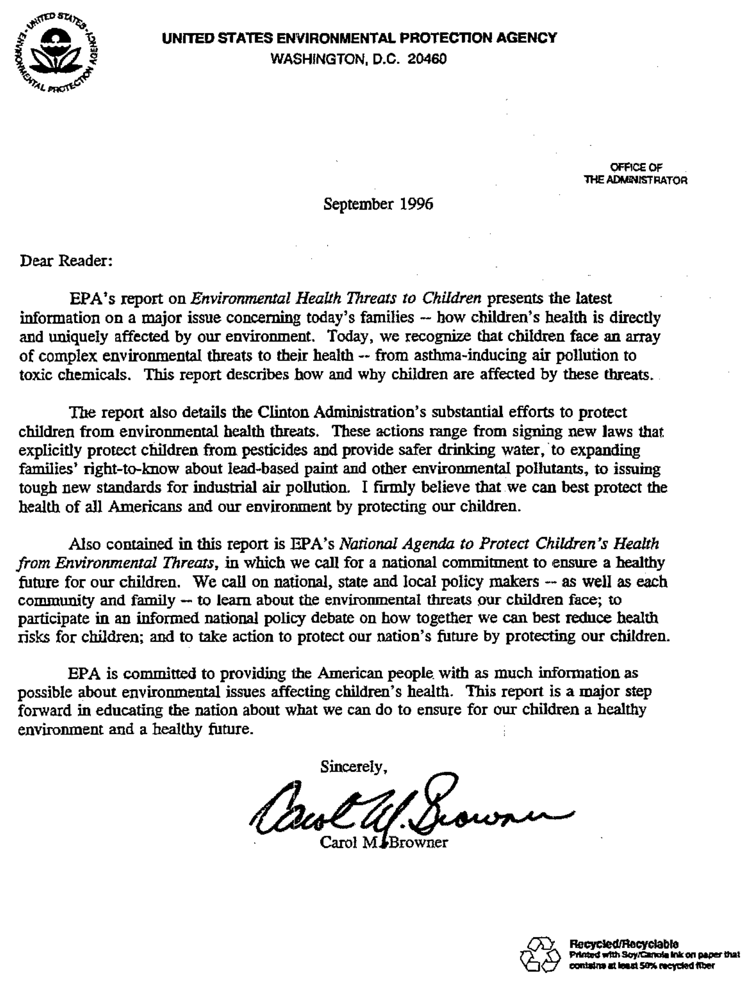
Administrator
(1101)

EPA 175-F-96-001
September 1996

EPA

Environmental Health Threats To Children



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

September 1996

Dear Reader:

EPA's report on *Environmental Health Threats to Children* presents the latest information on a major issue concerning today's families -- how children's health is directly and uniquely affected by our environment. Today, we recognize that children face an array of complex environmental threats to their health -- from asthma-inducing air pollution to toxic chemicals. This report describes how and why children are affected by these threats.

The report also details the Clinton Administration's substantial efforts to protect children from environmental health threats. These actions range from signing new laws that explicitly protect children from pesticides and provide safer drinking water, to expanding families' right-to-know about lead-based paint and other environmental pollutants, to issuing tough new standards for industrial air pollution. I firmly believe that we can best protect the health of all Americans and our environment by protecting our children.

Also contained in this report is EPA's *National Agenda to Protect Children's Health from Environmental Threats*, in which we call for a national commitment to ensure a healthy future for our children. We call on national, state and local policy makers -- as well as each community and family -- to learn about the environmental threats our children face; to participate in an informed national policy debate on how together we can best reduce health risks for children; and to take action to protect our nation's future by protecting our children.

EPA is committed to providing the American people with as much information as possible about environmental issues affecting children's health. This report is a major step forward in educating the nation about what we can do to ensure for our children a healthy environment and a healthy future.

Sincerely,

Carol M. Browner

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Executive Summary

Protecting Our Children Is Fundamental

Protecting our children is one of the Clinton Administration's highest priorities. Healthy children and strong families are fundamental to the future of our nation. Protecting our environment is critical to our children's health today, and lays the groundwork for a healthier future for their generation, and for generations to come. As a nation, we must remain vigilant about protecting our children from environmental hazards—which we now recognize pose many unique threats to children's health. This report outlines the status of children's environmental health; sets forth Environmental Protection Agency (EPA) accomplishments in protecting children from environmental health risks; and puts forward EPA's agenda that challenges the nation to ensure our children's healthy futures.

Children Are Particularly Vulnerable to Environmental Health Risks

For several years, the Clinton Administration has recognized and worked to improve our understanding of how children are at increased risk from many environmental threats, compared to adults. Children are particularly at risk from environmental hazards in three ways:

- Because children's systems are still developing—including rapid changes in growth and development, immature body organs and tissues, and weaker immune systems in infancy—they are more susceptible to environmental threats.
- Because children eat proportionately more food, drink more fluids, and breathe more air per pound of body weight, and because they play outside more, they are more exposed to environmental threats.
- Because children are least able to protect themselves, their behavior—such as crawling on the ground or the floor—exposes them to different environmental hazards.

Children Face a Wide Array of Environmental Hazards

Children today face significant and unique threats from a range of environmental hazards. Government and its partners have never faced a more complex challenge in protecting children. Environmental health hazards that threaten children range from asthma-inducing air pollution and lead-based paint in older homes, to treatment-resistant microbes in drinking water and persistent industrial chemicals that may cause cancer or induce reproductive or developmental changes. Just as the nation rose to meet the challenge of uncontrolled industrial pollution over the past 25 years, so too should we now commit to meet this new and critical challenge for our future.

The Clinton Administration Has Acted to Protect Children from Environmental Risks

The Clinton Administration has made great strides in protecting children. The Administration's new policy ensuring consideration of special environmental threats to children in the development of risk assessments, as well as its research agenda focusing on food pesticides and other exposures unique to children are among the many efforts the Clinton Administration has made to improve protection of children's health, based on cutting-edge science.

The centerpiece of EPA's effort has been Administrator Carol M. Browner's national policy, announced on October 23, 1995, to consistently and explicitly take into account health risks to children and infants from environmental hazards when conducting assessments of environmental risks. This new policy directly responds to issues raised by the National Academy of Sciences 1993 report, *Pesticides in the Diets of Infants and Children*, and is an extension of Administrator Browner's efforts to make children's health a priority throughout the Agency.

The Clinton Administration also has made children's health issues a high priority across all of EPA's work, including: drinking water protections; toxic waste cleanups; toxic air pollution reduction; protections for rivers, lakes and streams; safety controls for toxic chemicals used at home; lead poisoning prevention; enforcement of environmental laws; and, most critically, use of the best scientific research to answer the many questions that remain about how children's health is affected by environmental hazards.

Responding swiftly to recommendations in the National Academy of Sciences 1993 report, the Clinton Administration took unprecedented steps to protect the health of children from the risks posed by pesticides in their food. The Administration committed to ensuring the safety of foods our children eat by considering children's unique exposures and risks, and by reducing the overall use and risks of pesticides in the United States. EPA has intensified its efforts to: reduce the use of high-risk pesticides; increase the research and testing needed to learn more about children's exposure to pesticides in food; and establish new standards to protect children and infants from dietary health risks posed by pesticides. EPA also is expanding its assessment of the effects from substances on children's neurological, endocrine, and immune systems.

More Remains to be Done

The array of environmental threats facing children today—and the uncertainties in the adequacy of current protections derived principally to protect adults—will require great care and commitment to address. We recognize that children's environmental health issues are a top priority and must become a central focus of all EPA's efforts.

We thus challenge our partners in industry, governments, Congress, academics, health professions and interest groups to commit to adopt and help to implement EPA's

National Agenda to Protect Children's Health From Environmental Threats.

To meet this challenge, the Administration will:

1. As a national policy, ensure that all standards EPA sets are protective of the potentially heightened risks faced by children, and that the most significant current standards be re-evaluated as we learn more;

2. Identify and expand scientific research opportunities on child-specific susceptibility and exposure to environmental pollutants so that the best information can be employed in developing protections for children;

3. Develop new, comprehensive policies to address cumulative and simultaneous exposures faced by children—analogous to the goal of EPA's Common Sense Initiative—moving beyond the chemical-by-chemical approach of the past;

4. Expand community right-to-know—building on successes under the current law and expanding the available tools through a Family Right-to-Know Initiative—to allow families to make informed choices concerning environmental exposures to their children;

5. Provide parents with basic information so they can take individual responsibility for protecting their children from environmental health threats in their homes, schools, and communities;

6. Expand educational efforts with health and environmental professionals to identify, prevent, and reduce environmental health threats to children; and

7. Commit to provide the necessary funding to address children's environmental health issues as a top priority among relative health risks, as started in the President's Fiscal Year 1997 Budget.

EPA's **National Agenda to Protect Children's Health from Environmental Threats** will, together with the efforts of our partners, ensure that children receive the protection they need and deserve, and help our nation fulfill its obligation to protect future generations.

EPA's National Agenda to Protect Children's Health from Environmental Threats

I. The Problem

The Clinton Administration has recognized and worked to improve its understanding of how children are more at risk from many environmental threats than adults. Children are particularly at risk from environmental hazards in *three* ways:

- **Because children's systems are still developing, they are more susceptible to environmental threats.** Children move through several stages of rapid growth and development, from infancy through adolescence. Exposure to toxic substances can affect fetal, infant, and childhood growth, impairing development of their nervous systems, and causing abnormal development because of hormonal or immunologic effects. Infant immune systems are less well developed, so, for example, they may be less able than healthy adults to recover rapidly from microbes found in drinking water, such as *cryptosporidium*.

- **Because children eat proportionately more food, drink more fluids, breathe more air, and play outside more, they are more exposed to environmental threats.** Children eat more calories, drink more water and breathe more air per pound of body weight than adults do, and thus may ingest more pollutants per pound of body weight. They eat far larger amounts of certain foods for their body weight than adults. Their immature skin and body tissues risk greater damage from the sun, and can more readily absorb many harmful substances.

- **Because children are least able to protect themselves, their behavior exposes them to different environmental hazards.** Children's natural curiosity and tendency to explore leaves them open to health risks adults can more easily avoid. When young children crawl on the ground or the floor or play outside, they are more exposed to potentially contaminated dust and soil, lead paint, household chemicals, garden chemicals, and other potentially hazardous substances.

II. Environmental Health Threats to Children

We now recognize the **magnitude** of these healths threats to our children. Asthma, for example is now the leading cause of hospital admissions for our nation's children. Children face a wide array of major environmental health threats, including these areas:

- **Lead poisoning** is a top environmental health hazard for young children, **affecting as many as 1.7 million children age five and under,** according to Centers for Disease Control and Prevention (CDC) data. Although lead-based house paint has long since been taken off the market, children living in older homes are threatened by chipping or peeling lead paint, and excessive amounts of lead-contaminated dust. **More than 80 percent of U.S. homes built before 1978–some 64 million—contain lead paint.** Lead poisoning in children causes IQ deficiencies, reading and learning disabilities, impaired hearing, reduced attention spans, hyperactivity, antisocial behavior, and other problems.

- **Pesticides** pose a risk for children both as household chemicals and in food, particularly because children consume higher amounts of fresh produce than adults. Some pesticides can cause cancer, central nervous system damage, or respiratory illness. **Each year, more than 100,000 children accidentally directly ingest pesticides.** EPA receives an average of 24,000 pesticide hotline calls each year, two-thirds of which are from parents concerned about pesticides' dietary or household risks for children.

- **Asthma** deaths are on the rise in children and young people, **increasing by a dramatic 118 percent between 1980 and 1993,** according to the CDC. Many of the most common air pollutants can cause or contribute to respiratory illnesses, including asthma, which is now the leading cause of hospital admissions for our nation's children. **More than 25% of the nation's children live in areas that don't meet national air quality standards.**

- **Drinking water contaminants** pose a risk to children, particularly to infants, who drink more fluids per pound of body weight—and who may be more vulnerable to the effects of microbial contaminants like *cryptosporidium*. **EPA estimates that last year, a total of 30 million Americans drank water from systems that violated one or more public health standards—and roughly 13 million of them** are served by systems that do not filter their water and thus may not adequately protect against microbial contaminants. In Milwaukee in 1993, hundreds of thousands of residents became severely ill and 100—including children—died after the drinking water became contaminated with *cryptosporidium*.

- **Polluted waters** not only affect children when they swim in our lakes and streams, but also when they eat certain freshwater fish. Hundreds of beaches are closed each summer due to raw sewage and other contamination. All over America, warning signs are posted near thousands of rivers, lakes and streams, raising special concerns that pregnant women, children, and others with sensitive or compromised immune systems should not eat fish caught in the water because of contamination. **From January to September 1994, some 1,500 fish advisories were posted—with 73 percent of them related to mercury contamination.** Exposure to high doses of methyl mercury during pregnancy and the first few months of life may pose particular threats to a child's developing nervous system.

- **Toxic waste dumps** are a neighborhood blight and a health hazard to our communities, especially to our children. Parents should not have to worry that their children will be exposed to toxic waste when playing in their neighborhood, yet **one in four Americans—including 10 million children under the age of 12—lives within four miles of a toxic waste dump** and our cities are littered with thousands of abandoned industrial sites.

- **PCBs**, or polychlorinated biphenyls, were banned by EPA in 1976 because they cause cancer; some 20 years later, however, this toxic chemical continues to persist in the environment, often in contaminated fish. **Children whose mothers have high levels of PCBs when pregnant may develop learning disabilities and experience delayed development.**

- **Second-hand tobacco smoke** dramatically affects children. A recent CDC study estimates that **children exposed to tobacco smoke in their homes have 16 million more days of restricted activity, 10 million more days of bed confinement, and miss 7 million more school days** annually than other children, primarily due to acute and chronic respiratory conditions.

- **Overexposure to the sun's harmful ultraviolet light** can damage children's skin as they spend time playing outdoors. The American Academy of Dermatology estimates that up to 80% of a person's lifetime exposure to potentially damaging ultraviolet light occurs before the age of 18. Ultraviolet rays pose a threat to children because severe sunburns experienced in childhood increase the likelihood of developing malignant melanoma, the most deadly kind of skin cancer. Last year there were an estimated one million new cases of skin cancer in the United States.

Children also face several environmental risks that we are just beginning to understand more fully:

- **Potential Effects on the Endocrine System from Pesticides and Industrial Chemicals:** In recent years, increasing scientific and public attention has been focused on the potential effects of synthetic chemicals on the hormone system. These chemicals—which have been labeled "endocrine disruptors"—may pose a major health concern for children. Although there is considerable scientific uncertainty, it is clear that a number of chemicals, including organochlorine pesticides such as DDT and chemicals such as PCBs, can cause endocrine disruption in wildlife and laboratory animals. Because very low levels of chemicals that block or mimic reproductive and thyroid hormones can determine the course of prenatal development, concern exists about the potential for birth defects and alterations of normal growth and development in children. Endocrine disruptors may also play an important role in reproductive cancers.

- **Potential Effects from Particulate Matter Air Pollution:** Epidemiological studies indicate that exposure to particulate matter—fine particles in the air, such as soot or dust—at levels below the current national ambient air quality standard can be associated with adverse effects on public health. Studies have identified children as a sensitive population to particulate matter, both in general and for those with respiratory illness. Reports of restricted activity days, school absences, increased respiratory symptoms, and decreased lung function have all been associated with children's exposure to particulate matter.

III. The Clinton Administration Has Acted to Protect Children from Environmental Health Risks

The Clinton Administration has achieved important progress in improving environmental health protection for our children. From its new policy emphasizing the need to ensure that environmental threats to children are considered when conducting risk assessments, to its research agenda focusing on food pesticides and other exposures that are unique to children, the Administration has been on the cutting edge of protective science.

Under President Clinton's leadership, EPA and other federal agencies are making children's health considerations a priority in all of their work to protect public health and the environment, including work to: set strong environmental and public health standards and protections; educate the public and ensure the public's right to know; and conduct research to answer the many questions that remain about how children's health is affected by environmental problems.

The centerpiece of EPA's effort is the Administrator Carol M. Browner's national policy, announced on October 23, 1995, to consistently and explicitly take into account the health risks to children and infants from environmental hazards when conducting environmental risk assessments. This new policy directly responds to issues raised by the National Academy of Sciences 1993 report, *Pesticides in the Diets of Infants and Children*, and is an extension of Administrator Browner's efforts to make children's health a priority throughout the Agency.

A. Applying the Best Science to Protect Our Children's Future

The Clinton Administration has worked conscientiously to ensure sound scientific underpinnings for its policy initiatives on protecting children. It is critical that the best science be applied to these problems; that the research be of the absolute highest integrity and caliber; that it be on the cutting-edge in sophistication, allowing for consideration of the special mechanisms that affect children as well as differences in susceptibility, and not just whether an effect to the general population occurs; and that it focus on the issues of greatest risk and concern.

Emblematic of EPA's efforts has been the **development of a cluster of new risk assessment and testing protocol guidelines.** These help ensure that assessments are conducted using a consistent set of standards and a framework that requires a focus on the unique factors exhibited by infants and children. EPA has recently proposed new guidelines for assessing cancer-causing substances and neurotoxicological effects. Guidelines for evaluating reproductive toxicity will be issued later this year. EPA has also recently proposed new test guidelines for the evaluation of chemicals that focus on developmental toxicity and reproductive toxicity testing. All of these require a sophistication in scientific evaluations that looks at the impacts of environmental agents on mechanisms that specifically may affect infants, children, fetuses, and the ability to bear children.

EPA research priorities have a special focus on issues affecting children's health. From work on microbial drinking water contaminants and support for research on urban air issues, to consideration of reproductive and developmental effects of endocrine disruptors, EPA's research priorities are an important part of its agenda focused on children. Included among the Administration's efforts are:

Focusing Toxic Air Pollution Research

Asthma—both individual episodes and asthma-related deaths—is increasingly on the rise in children and young people. Ongoing research sponsored by the Administration is expected to provide new information critical to understanding how air pollution affects the development of asthma in children. A special effort funds research that focuses on the link between health effects and exposure to toxic urban air pollution. EPA is funding studies that identify whether special subpopulations—such as infants and children—are at increased health risks due to higher exposure to toxic urban air pollution, or due to their inherent biological sensitivities. These community-based efforts will examine the pattern, frequency, and magnitude of exposures in specific communities.

Defining the Risks of Microbial Contaminants in Drinking Water

To ensure that the water our children drink is safe from contaminants that pose the greatest threat to their health, our immediate priority is increasing our understanding of microbial contaminants, most notably *cryptosporidium*. A number of epidemiological surveys and day-care-center outbreaks have shown that young children, especially those under the age of two, may be more susceptible to *cryptosporidium*-related illness. EPA has launched new monitoring and treatment programs and is participating in scientific efforts to find answers about deadly parasites like *cryptosporidium*, including how we can better test for them, how people are exposed to them through water, and how to develop effective treatment programs. EPA is also working with the Centers for Disease Control and Prevention and others to assure that the risks associated with *cryptosporidium* are communicated clearly and accurately, particularly to protect those with sensitive immune systems, including infants.

Improving Scientific Knowledge About Children's Exposure to Pesticides

A 1993 National Academy of Sciences report, *Pesticides in the Diets of Infants and Children,* concluded that then-current scientific and regulatory approaches did not adequately protect infants and children from pesticide residues in food. The Academy called on EPA to make significant changes in assessing exposure to pesticides, analyzing the potential for harmful or toxic effects, and using these data to characterize actual risks. Thus, the Academy report provided a major challenge to EPA to improve the safety of our food supply and provide greater assurance that our children are protected. The Clinton Administration moved aggressively and rapidly to respond to the Academy report with a sweeping joint effort by EPA, the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA) to carry out the Academy recommendations.

Basing Pesticides Standards on Children's Actual Exposures

EPA is expanding its Pesticides in Children Research Program. In FY97, EPA will conduct a survey of children's exposure to pesticides through air, water, food, and dust in homes, schools, day care facilities, and other areas. From characterizing children's activity patterns to addressing toxic effects as a function of age—including response as a function of critical periods of neurological and immunological development—EPA will be better equipped to understand the special problems affecting children.

The National Academy of Sciences report recommended that EPA take into account children's unique dietary patterns when setting pesticide standards and registrations. EPA now routinely considers dietary risk to infants and children in registering and re-registering pesticides. In some cases, the Agency determines that risks to children are unacceptable, resulting in the denial of permission to use certain pesticides or voluntary withdrawal. The U.S. Department of Health and Human Services (HHS), USDA, and EPA are designing new surveys to improve our knowledge of what infants and children eat. And EPA is also improving its methods of analyzing the component parts of food as it is eaten (for example, pizza is made up of wheat, tomatoes and milk), so that exposure to pesticide residues can be estimated more reliably.

The Academy also recommended that EPA account for other exposures to the same pesticides found in children's diets, to create a more complete picture of the unique risks children face. EPA now uses an approach to risk assessment that examines children's multiple routes of exposure to pesticides at home and in schools, as well as in food. EPA also has developed a new method for assessing acute—or short-term—exposures to toxic pesticides, improving the Agency's ability to prevent children from being exposed to pesticide residues that can cause illness after only a single serving of the food is consumed.

The National Academy of Sciences report also recommended improvements in monitoring and tracking pesticide residues on the food children most frequently eat. Since 1993, EPA, FDA, and USDA and the states of California and Florida have been developing a National Pesticide Residue Database to compile in one place all data on pesticide residues gathered from monitoring of food throughout the U.S. The Academy recommended this step to provide a more reliable picture of pesticide residues in our food. FDA and USDA food monitoring programs have been redesigned to emphasize monitoring of food that is particularly important in children's diets, such as pears, apples, tomatoes, rice, and peas.

Conducting Better Assessment of Risks Unique to Children

The National Academy of Sciences report recommended a full assessment of unique risks to children because of growth and developmental vulnerabilities. EPA is moving to require pesticide and chemical manufacturers to conduct new tests needed to assess potential toxic effects of pesticides on the immune system, the nervous system, reproduction and development, and the visual system of children.

Setting Standards Based on Combined Exposures of Chemicals with the Same Mode of Action

The National Academy of Sciences report concluded that many pesticides on the market act in the same or similar ways—both in their effectiveness as pest controls and in the health effects they cause in humans. Yet EPA regulates these chemicals one at a time. EPA has begun to phase in an assessment process that will fully capture the combined risk posed by such chemicals, starting with a special review for the triazine herbicides.

Researching Potential Effects on the Endocrine System from Pesticides and Industrial Chemicals

In recent years, increasing scientific and public attention has been focused on the potential effects of synthetic chemicals on the hormone system. EPA has acted to ban many of these chemicals—including DDT and PCBs—and has already taken many steps to regulate over 95% of known sources of dioxin in the U.S. In addition, the Clinton Administration is involved in important research to try to better understand increasing reports of reproductive, developmental and other problems linked to some chemicals, including processes that may uniquely affect children. The Administration is continuing to develop a national research strategy, developing new strategies—

with the involvement of stakeholders—for areas like pesticide and chemical screening, testing and controls. EPA's research in FY97 will focus on important questions to determine: classes of chemicals that may affect the endocrine system; how much exposure produces adverse effects; how humans and wildlife are exposed; effects actually occurring in humans and wildlife; and the combined effects of exposure to multiple endocrine disruptor chemicals.

Improving Scientific Knowledge About Fine Particle Air Pollution

In FY97, EPA will significantly expand its research program on particulate matter air pollution. Research will be conducted to identify the way in which particles affect human health, the critical exposure concentrations, and the sizes, chemical compositions, and sources of particles responsible for health effects. Research also will begin to investigate technologies and control practices to reduce fine particles.

Improving Scientific Knowledge About Mercury

Mercury in its organic form can produce a variety of health effects depending on the amount and timing of exposure. Data from both humans and experimental animals indicate that methylmercury disrupts the development of nervous systems, and is of particular concern during the prenatal and postnatal period. These effects may occur at lower levels of exposure for children and fetuses.

EPA is examining the extent of these environmental concerns. A draft report to Congress on mercury, including analysis of exposure routes and risk characterization, is undergoing peer review by EPA's independent Science Advisory Board. EPA also is closely monitoring the findings of ongoing human studies related to exposures to methylmercury and their impact on nervous system development. EPA will be refining its Oral Reference Dose to set a standard for exposure.

B. Setting Strong Standards and Taking Tough Actions to Protect Children's Health

The Clinton Administration has made great strides in focusing EPA's efforts on matters of significant consequence to children's environmental health and in setting environmental standards that will be adequately protective. Among the Administration's accomplishments are:

Protecting Children from Toxic Lead Poisoning

One of the greatest steps in protecting children's health was EPA's ban on lead in gasoline twenty years ago and the Consumer Product Safety Commission's ban on lead in paint—resulting in a **98% reduction in lead levels in the air and protecting millions of children from serious, permanent learning disabilities** by helping to reduce blood lead levels by 75 percent, according to CDC data.

Today, however, **lead poisoning is still a leading environmental health hazard for young children,** affecting as many as 1.7 million children age five and under—one out of every 11. Although lead-based house paint has long since been taken off the market, children living in older homes are threatened by chipping or peeling lead paint, or excessive amounts of lead-contaminated dust. More than 80 percent of homes built before 1978 contain lead paint. Even at low levels, lead poisoning in children can cause IQ deficiencies, reading and learning disabilities, impaired hearing, reduced attention spans, hyperactivity and other behavior problems. Pregnant women poisoned by lead can transfer lead to a developing fetus, resulting in adverse developmental effects.

To address this most pressing remaining need in lead poisoning prevention, EPA works with the U.S. Departments of Housing and Urban Development (HUD) and Health and Human Services (HHS) to ensure that the nation's housing is "lead safe." The Clinton Administration has expanded this initiative to include: the control of hazardous lead paint in housing where children live; research on lead poisoning and lead abatement; training and certification of lead removal workers to ensure effective abatement; public education on the health risks posed by lead paint, particularly targeted to parents and children; and enforcement efforts.

Protecting Children from Pesticides

Going beyond the recommendations of the 1993 National Academy of Science's report, the Clinton Administration launched a major effort to improve the safety of food for children, while the work to carry out the Academy's recommendations is underway. These efforts include three major components:

- **Strengthening Pesticide Standards to Limit the Health Risk to Infants and Children:** In August 1996, President Clinton signed an across-the-board strengthening of our nation's food safety laws (Food Quality Protection Act) which included three important Administration-recommended reforms: a stronger health-based standard to limit the risks of pesticide exposure; special protections for infants and children; and expansion of the consumer's right-to-know about pesticide risks.

- **Reducing the Risks—and Minimizing the Use—of Pesticides Now:** To speed the reduction of pesticide risks—even while awaiting the results of new and emerging scientific data—EPA, FDA and USDA have pledged to take several steps to reduce pesticide use overall. These include: ensuring the availability of cost-effective methods of integrated pest management as an alternative to traditional pesticides; encouraging the use of biological pesticides and other alternatives; and working to achieve the goal that 75 percent of U.S. agricultural acreage will use some form of integrated pest management by the year 2000. Through a cooperative partnership, EPA is working with more than 40 pesticide users—including growers, utilities, and non-agricultural associations—to reduce environmental health risks from pesticides through laboratory research and improved management systems. Many of these partnerships are with growers of foods that children eat frequently, including potatoes, apples, citrus fruits, pears, peaches and tomatoes.

- **Getting Safer Pesticides on the Market Faster:** EPA has greatly accelerated its reregistration program for reevaluating and reducing risks associated with the older, often more toxic pesticides currently in use. Reevaluations are being done at a rate of 40 per year and are complete for 121 pesticide chemical cases, covering 65 percent of pesticide use in the U.S. In 1995, EPA significantly increased its registrations of new, "safer" or reduced risk pesticides. Twenty-four new active ingredients that are biopesticides or reduced-risk pesticide ingredients were approved for use, quadrupling the rate of approval of safer pesticides.

Protecting Infants from Microbial Contaminants in Drinking Water

Drinking water contaminants pose a particular risk to infants, who drink more fluids per pound of body weight—and whose immature systems may be more vulnerable to microbial contaminants such as *cryptosporidium*. To ensure that drinking water is safe for children, our immediate priority is control of microbial contaminants. The Clinton Administration has taken a number of steps to reduce health risks from microbial contaminants in drinking water systems across the nation:

- **Successfully proposed the first-ever state revolving fund to help achieve safer drinking water** through funds that go straight to the states for loans to communities to upgrade and improve their drinking water treatment facilities;

- Targeted safety standard development and available **resources to focus on contaminants in drinking water that pose the greatest threats to public health,** such as microbial contaminants, including *cryptosporidium*, and on special populations such as the elderly, children, people with HIV/AIDS, and others who are most at risk from unsafe drinking water. In August 1996, Congress passed new safe drinking water legislation which includes these principles based upon Administration recommendations.

- Required that large water systems test source water—and, in some cases, treated water—for *cryptosporidium*. Data from this 18-month test, along with information collected by EPA, will help **develop new safety rules and standards to protect further against** *cryptosporidium* and other microbials; and

- Launched the *Partnership for Safe Water* with the nation's water suppliers in March 1995, to achieve voluntary **improvements in surface water filtration plants** around the nation. Filtration substantially reduces—but may not entirely eliminate—*cryptosporidium* contamination.

The Clinton Administration is also working to bring clean running water to the children and families who live in the 1.4 million rural households across this country. With its *Water 2000* initiative, the Administration is working with states, companies, banks, and non-profit groups to bring safe, affordable drinking water to America's most remote and needy corners by the end of the century.

Protecting Children from Dangerous Air Pollution

Air pollution has long been implicated in childhood deaths and hospitalizations, and reduced quality of life resulting from respiratory trauma and disease. A number of studies have associated childhood exposure to air pollution (ground level ozone, particulate matter, sulfur dioxide, nitrogen dioxide) with increases in school absences, decreased lung function, and increased incidences of bronchitis and asthma. According to the CDC, **asthma is the most chronic childhood illness in the U.S., affecting some 4.8 million children below the age of 18.** Between 1980 and 1993, asthma alone accounted for 3,850 deaths among people under 24 years of age. During the same period, the annual age-specific death rate from asthma increased 118%, and the hospitalization rate increased 28%. Currently, **more than 25% of the nation's children live in areas that don't meet national air quality standards.**

EPA's air pollution control efforts, taking place largely under the Clean Air Act, are focused on protecting children and others from the harmful effects of air pollution by improving air quality in communities. The Agency develops health protective standards that set safe limits for the most prevalent pollutants, and works with the states and sources to implement those standards.

In the last three years, the Clinton Administration has put new pollution control requirements in place that dramatically lower both toxic and smog causing emissions from a variety of sources, including chemical plants, refineries, trucks and buses, large landfills, and gasoline. When combined with efforts at the state and local level, the result has **been an unprecedented number of communities achieving cleaner air** for their citizens to breathe as they come into compliance with the health based national air quality standards.

In particular, successful implementation of the acid rain provisions of the Clean Air Act have helped reduce substantially the particulate pollution implicated in recent studies as the cause of tens of thousands of premature deaths, as well as increases in hospitalization and illness in children. However, new scientific data on the effects of smog (both ozone and particulate matter) indicate the need to continue a strong focus on reducing exposure, especially childhood exposure, to these pollutants.

Other specific air pollutants such as mercury are particular threats to children because of damage to the nervous system that can occur during fetal and childhood development, among other concerns. Since 1993, the Administration has completed or begun developing requirements that would substantially reduce the emissions of mercury from the largest sources, including municipal waste combustors, medical waste incinerators, and hazardous waste incinerators. Over the next several years, the Agency also expects to complete and issue a study on mercury emissions from other sources, including coal-fired power plants.

The Administration has also issued new, more protective controls on air emissions from incinerators that burn hazardous waste—a process that can result in emissions of dioxin, a family of toxic chemicals that causes cancer in animals. The **99% reduction in dioxin emissions achieved** by these rules has special protective benefits for nursing infants, because dioxin and other bioaccumulative chemicals concentrate at higher levels in breast milk.

The Clinton Administration has maintained a strong commitment to the phasing out of stratospheric ozone depleting substances, the primary way to limit the increase in ultraviolet radiation that reaches the earth. This commitment has particular benefits for children, as the American Academy of Dermatology estimates that up to 80% of the lifetime exposure to potentially damaging ultraviolet radiation occurs before age of 18. The likelihood of developing malignant melanoma, the most deadly kind of skin cancer, is linked to the number of severe sunburns experienced in childhood. The Administration will continue to work with the international community to complete these phaseouts.

Protecting Children from Exposure to Carelessly Dumped Toxic Waste

The Clinton Administration has moved aggressively to address the threat to children from toxic and industrial waste sites in communities. To clean up toxic waste sites, the Clinton Administration has fundamentally redirected the Superfund toxic waste cleanup program to make it faster, fairer and more efficient. Cleanups have been dramatically accelerated: **in the past two years, nearly as many Superfund cleanups were completed in each of the past two years than in the program's entire first decade.** EPA and the Agency for Toxic Substance Disease Registry are collaborating on a children's health initiative that will further enhance the prevention of exposure to hazardous substances released from Superfund sites. Together with businesses and communities, the Administration also is cleaning up the old industrial properties — the so-called "brownfields" that lie idle in the middle of urban neighborhoods—so that they can be redeveloped and returned to a revitalized community. The President has proposed a Brownfields Tax Incentive to help leverage more than $10 billion in private cleanups at these sites.

The Clinton Administration also is **aggressively enforcing anti-pollution laws to avoid threats to the health and safety of our children from illegal dumping of toxic waste.** Not long ago in Florida, two children died because they inhaled a toxic chemical illegally dumped near an open lot where they were playing. The Clinton Administration has consolidated and toughened EPA's environmental enforcement program to improve compliance with environmental laws and to penalize polluters who break these laws.

Protecting Mothers and Infants from Contaminated Fish and Polluted Waters

Clean water is America's first line of defense in protecting our children's health. Americans need clean safe water for drinking and swimming. Polluted waters not only affect children when they swim in our lakes and streams, but also when they eat certain fish from these areas. PCBs and mercury continue to persist in the environment, often taken up by fish. Children whose mothers are exposed to high levels of PCBs or mercury when pregnant may develop learning disabilities and experience delayed development.

The Clinton Administration has funded actions in thousands of communities across the country to protect and restore our rivers and lakes and coastal areas. The Clinton Administration also has acted to protect the nation's largest body of fresh water with its **Great Lakes Water Quality Initiative.** This landmark effort establishes consistent, common-sense, cost-effective guidelines to protect the Great Lakes—which constitute 95% of the nation's fresh water and provide drinking water for 23 million Americans. By addressing the long-term toxic pollution that persists in the Great Lakes, this initiative is protecting children and families by decreasing their exposure to toxic pollutants that can pose particular health effects on reproduction, and children's development and immune systems.

In addition to working with the states to implement the Guidance, EPA has undertaken a number of specific activities to **reduce sources of PCB and mercury contamination.** EPA has brought together all of its programs to develop an integrated strategy, and has undertaken particular efforts in the Great Lakes and to control emissions jointly with our North American neighbors. For example, EPA has been working to encourage the voluntary phase out of electrical equipment with contain PCBs.

As a result, 12 major utility companies have reported that they have removed almost 90 percent of PCBs from their equipment.

C. Expanding Community Right-to-Know and Public Education to Provide Tools for Families to Make Informed Choices

The Clinton Administration has vigorously expanded the public's right-to-know about pollutants in their community. It is essential that families and communities have the tools with which to make informed decisions concerning their environment and any potential health risks they may face and that industry disclose its toxic pollution.

President Clinton has used his powers to expand and strengthen the Community Right-to-Know laws.

The Administration in a 1993 rulemaking nearly doubled the number of chemicals on which industry must report—adding 286 chemicals. These expansions were protected against Congressional efforts to undermine them when the President issued a Pollution Disclosure Executive Order in August 1995, requiring federal contractors to meet EPA's pollution disclosure standards. In June 1996, the Administration expanded the categories of facilities required to disclose information about toxic releases by 30 percent—bringing the total to more than 31,000 facilities that must report their toxic emissions to the public.

Further expansions to community right-to-know are being planned to provide families with more complete information about toxic chemicals being released in their neighborhoods—including expanding the type of information reported to provide critical information about industry's use of toxic chemicals.

In keeping with right-to-know, EPA has also expanded public access to Agency information—particularly Internet access. Armed with this information, parents can work to reduce and prevent pollution within their neighborhood and protect the health of their children and their community's children.

The Clinton Administration successfully proposed giving every American the right to know about tap water contaminants.

In August 1996, President Clinton signed new drinking water legislation that provides strengthened protections to ensure that American families have clean, safe tap water—improvements that the Clinton Administration has called for since 1993—including provisions to improve consumer information about local tap water. The new law gives Americans access to direct, simple information about local water quality, water sources, contaminants, and whether the water poses a risk to health.

The Clinton Administration successfully recommended new measures to expand consumers' right to know about pesticide health risks.

New food safety legislation, signed by President Clinton in August 1996, provides a comprehensive overhaul to strengthen the nation's food safety system that regulates pesticides on foods—reforms that the Clinton Administration has urged since 1993. To ensure that Americans have both comprehensive health protection and the tools they need to protect themselves and their families from pesticide risks, the new law includes special right-to-know provisions that provide more public information than ever before about risks from pesticides on foods.

The Clinton Administration has taken steps to protect children from lead-based paint poisoning.

The Clinton Administration has taken steps to protect children from lead-based paint poisoning by ensuring that parents have the right to know about lead-based paint hazards when they buy or rent a home. As part of the Administration's community right-to-know efforts, EPA and HUD recently took action to require sellers and landlords to disclose any known lead-based paint to home buyers, allowing them the option of conducting a lead hazard assessment. Approximately 64 million dwellings—all built before 1978—contain some lead-based paint, although much of it can be managed and maintained safely buy using simple, low-cost common sense procedures. Particularly at risk are families renovating older structures and low-income families living in dilapidated housing. Parents can unknowingly poison their children when they disrupt lead-based painted surfaces during renovations, for example. This new effort will provide the tools to assist families in avoiding lead contamination.

The Clinton Administration is moving to prevent dangerous ultraviolet light overexposure through education and information.

Ultraviolet radiation overexposure poses significant risks to children because sunburns experienced in childhood are linked to the onset of skin cancer later in life. EPA, along with the National Weather Service and the Centers for Disease Control and Prevention instituted the federal UV Index program. The Index, which is expressed as a number between 0 and 10+, is made available daily in 58 cities nationwide. Developed in cooperation with medical organizations, broadcast meteorologists, and educators, the UV Index program is giving people the information they need to protect themselves and their children from overexposure to the sun.

The Clinton Administration is providing Americans with more information about contaminated fish.

EPA has developed a database of fish consumption advisories which is available to the public. The "National Listing of Fish Consumption Advisories" includes all available information describing state-issued fish consumption advisories in the United States. Included in the database is information on the geographic location of the advisory, species of fish of concern, chemicals, and segments of the population that are affected.

In the Great Lakes, levels of bioaccumulative toxic substances in fish are lower than in the early 1970s, however, the levels still justify issuance of public health advisories regarding fish and wildlife consumption. Specific advisories are also issued that apply to vulnerable consumers, such as children and women who anticipate bearing children. EPA, the Agency for Toxic Substances and Disease Registry, the Great Lakes states and EPA's other partners will continue to research the health implications and impacts of consuming contaminated Great Lakes fish.

EPA is providing information to help parents and teachers prevent environmental risks to children.

EPA has worked to educate parents and teachers about potential environmental risks and how to avoid them. EPA has produced a number of consumer information kits on preventing exposures around the home to lead, radon, and other indoor air contaminants and pesticides. EPA has directed a number of efforts toward schools, notably the *Tools for Schools* kit for protect the indoor air environment in schools and the *Integrated Pest Management in the Schools* kit for reducing the need for and the use of hazardous pesticides.

The Clinton Administration is seeking ideas to make informational labels on toxic products clearer and more protective.

EPA recently initiated a Consumer Labeling Initiative to expand the amount of hazard and health information on pesticide and related consumer product labels, analogous to the new food nutrition labels. EPA also is working on this effort with the Consumer Product Safety Commission and the Food and Drug Administration, and a number of leading industry groups and companies, as well as parents, health professionals, and others.

IV. EPA's National Agenda to Protect Children From Environmental Health Threats:

Recommended Actions

Children today face significant and unique threats from a range of environmental hazards. Governments and its partners have never faced a more complex challenge in protecting children, due to environmental health hazards that range from asthma-inducing air pollution and lead-based paint in older homes, to treatment-resistant microbes in drinking water and persistent industrial chemicals that may cause cancer or induce reproductive or developmental changes. As the nation rose to meet the challenge of uncontrolled industrial pollution over the past 25 years, so too should we now commit to meet this new and critical challenge for our future.

The array of environmental threats facing children today—and the uncertainties in the adequacy of current protections derived principally to protect adults but that may not do enough to protect our children—will require great care and commitment to address. **We recognize that children's environmental health issues are a top priority and must become a central focus of all of EPA's efforts to protect public health and the environment.**

We thus challenge our partners in the private sector, throughout the many levels of government, in Congress, in academia, and in interest groups to commit to adopt and help to implement **EPA's National Agenda to Protect Children's Health From Environmental Threats.** To meet this challenge, the Administration will:

1. As a national policy, ensure that all standards EPA sets are protective enough to address the potentially heightened risks faced by children—so as to prevent environmental health threats wherever possible—and that the most significant current standards be re-evaluated as we learn more. It is essential that our national pollution control standards protect our nation's most valuable future resources, placing children at the center of our protection efforts, and that these standards be grounded in the best scientific information available. The Clinton Administration will move aggressively to adopt this policy. In addition, EPA will select—with public input and scientific peer review—five of its most significant public health and environmental standards to reissue on an expedited basis under this new policy.

2. Identify and expand scientific research opportunities on child-specific susceptibility and exposure to environmental pollutants so that the best information can be employed in developing protections for children. The Clinton Administration has worked conscientiously to ensure sound scientific underpinnings for its policy initiatives on protection children. It is critical that the best science be applied to EPA's efforts to address these problems: that the research be of the absolute highest integrity and caliber; that it be on the cutting-edge in sophistication, allowing for consideration of the special mechanisms that affect children, and not just whether an effect to the general population occurs; and that it focus on the issues of greatest risk and concern. Because growth and development are the primary tasks of childhood, EPA's research agenda will increasingly focus on the effects on growth and development, including intellectual and physical development. EPA will also have a special focus on windows for particularly damaging exposure from environmental insults in utero and in developing infants and children.

The Administration will continue to prioritize its research to have a special focus on issues affecting children's health. From work on microbial drinking-water contaminants, to supporting research on urban air issues, to considering reproductive and developmental effects of endocrine disruptors, EPA's research priorities are an important part of its efforts to better protect children.

EPA will also coordinate these efforts with the resources of other federal science agencies and work to foster academic and private sector research in these areas. To this end, EPA will challenge Congress to work with it to establish and fund two National Centers of Excellence on Children's Environmental Health at established medical institutions to provide a critical concentration of these efforts.

3. Develop new policies to address cumulative and simultaneous exposures faced by children—analogous to the goal of EPA's Common Sense Initiative—not just the chemical-by-chemical approach of the past. Among the areas of greatest scientific and regulatory need is the ability to discern real world circumstances—including the fact that children are exposed to many chemicals all at once and through multiple routes. Just as EPA has worked to integrate its authorities and approaches to particular industrial sectors through the Common Sense Initiative, so too must it address children's health issues through a similar effort that deals with the complexities of our modern industrial world in a realistic fashion and places children at the center of those considerations.

4. The dramatic results of the current Community Right-to-Know law—yielding substantial decreases in the emissions of toxic pollutants and empowering communities to be effective partners in working with industry to protect their communities' health and safety—should be built upon. The Clinton Administration is already working with Congress to guarantee the public's right to know about contaminants in drinking water. In addition, the Administration will continue its work to expand the categories of industrial facilities that report this information and the types of information—including data on chemical inputs and uses— that industry makes publicly available.

To enhance the usefulness of this information, it should be available for families to make informed choices about the products they use in their homes. The Clinton Administration will work with parents, scientists, the business community and the Congress to provide better information for families, so that they will have the tools to protect themselves. This proposal—**the Family Right to Know Initiative**—should provide common sense and cost-effective ways to meet the following principles:

- assist parents in assessing and avoiding unique environmental health risks to children from products and chemicals designed for child or home use;
- provide information on the whole range of environmental health risk from toxics, including cancer, developmental, endocrine and reproductive risks; and
- allow for informed consumer choices by providing improved information.

This initiative can be a major step forward in further protecting our children from environmental health risks. An informed family is best able to protect its child's health and future.

5. Call on American parents, teachers and community leaders to take personal responsibility for learning about the hazards that environmental problems pose to our children—and provide them with the information they need to help protect children from those risks at home, at school and at play. The Clinton Administration believes that an informed, involved local community will always do a better job of making environmental decisions than a distant bureaucracy—and never more so than when it comes to our children. Parents, teachers and community leaders can and should play a vital, day-to-day role in learning about the particular environmental hazards their children face in their own communities, and then use that knowledge to make more informed decisions that protect children and prevent environmental health problems.

Through its community right-to-know efforts, environmental education programs, and efforts to improve public access to information about environmental health hazards in the home, school and community, the Clinton Administration has greatly expanded the availability of information that parents, teachers and community leaders can use—in simple, everyday ways—to protect children's environmental health. This Agenda aims to take the next step: to make every effort to ensure that parents, teachers and community leaders take responsibility for learning about these risks, and to ensure that they have the information they need to take actions to protect children.

For example, through information already widely available from EPA, parents, teachers and community leaders can: learn about the amount and type of releases of toxic chemicals in their zip code area, and work with manufacturing facilities to reduce the amount of local pollution; improve indoor-air quality and reduce pesticides risks in school buildings, where children spend most of their days; purchase less toxic pesticides for use in the yard and garden, and use techniques to reduce the use of those products; learn about and test for radon and lead paint hazards before buying or renting an older home; learn about the availability of blood tests to measure lead levels for children at risk; find out about fish advisories issued in their community to avoid eating contaminated fish; and much more.

To advance personal responsibility and understanding of this important issue, EPA will expand its efforts to reach parents, teachers and community leaders so that they are aware of the need to know—and their right to know—more about the environmental health hazards our children face. The Clinton Administration also will expand its efforts to ensure that more information is made available through toll-free numbers, Internet access, environmental education programs and other means so that adults can make careful and informed decisions that will protect our children in every local setting, from the backyard to the schoolroom to the dinner table.

6. Expand educational efforts in partnership with health and environmental professionals to identify, prevent, and reduce environmental health threats. As recognized by the Institute of Medicine and leading groups such as the Children's Environmental Health Network and the National Environmental Education and Training Foundation, there is a pressing need to build routine awareness of environmental health threats into the training and medical practice of pediatric health professionals. EPA will work to expand its partnerships with these and other professional groups and other government agencies, particularly the CDC, to provide a continuing forum for exchange on these issues and to encourage development of appropriate curriculum and training materials essential for effective prevention of children's environmental health threats.

7. Commit to provide the necessary funding to address children's environmental health issues as a top priority among relative health risks, as started in the President's FY '97 Budget. The purest of intentions—or the most cynical of commitments based solely on appearances—are equally meaningless without the commitment of the resources that will be necessary to accomplish this ambitious Agenda. The Clinton Administration challenges Congress to meet this need by providing sufficient funding to EPA to carry out this Agenda. Our nation's commitment to this challenge can be measured only by the dedication of critical resources to achieve the goals outlined in EPA's Agenda. As demonstrated by the President's FY97 Budget, substantial resources dedicated to these efforts are critical. EPA's future budget submissions will contain specific line items for many of the elements of this Agenda.

EPA's **National Agenda to Protect Children's Health from Environmental Threats** will ensure that children receive the protection they need and deserve, and help our nation fulfill its obligation to protect future generations.

United States Government Accountability Office

GAO

Report to Congressional Requesters

January 2010

ENVIRONMENTAL HEALTH

High-level Strategy and Leadership Needed to Continue Progress toward Protecting Children from Environmental Threats

This Report Is Temporarily Restricted Pending Official Public Release.

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Highlights

Highlights of GAO-10-205, a report to congressional requesters

Why GAO Did This Study

Exposure to toxic chemicals or environmental pollutants may harm the health of the nation's 74 million children and contribute to increases in asthma and developmental impairments. In 2007, 66 percent of children lived in counties exceeding allowable levels for at least one of the six principal air pollutants that cause or aggravate asthma, contributing to medical costs of $3.2 billion per year, according to the Centers for Disease Control and Prevention.

In 1997, Executive Order 13045 mandated that agencies place a high priority on children's risks and required that policies, programs, activities, and standards address those risks. In response, the Environmental Protection Agency (EPA) created the Office of Children's Health Protection and convened the Children's Health Protection Advisory Committee.

This report assesses the extent to which EPA has institutionalized consideration of children's health through (1) strategies and priorities, (2) key offices and other child-focused resources, and (3) participation in interagency efforts. GAO reviewed numerous documents and met with EPA and other officials for this report.

What GAO Recommends

GAO recommends improvements to help EPA protect children, and EPA agreed to implement them. GAO also suggests that Congress consider reinstating a government-wide task force on children's environmental health.

View GAO-10-205 or key components.
For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

January 2010

ENVIRONMENTAL HEALTH

High-level Strategy and Leadership Needed to Continue Progress toward Protecting Children from Environmental Threats

What GAO Found

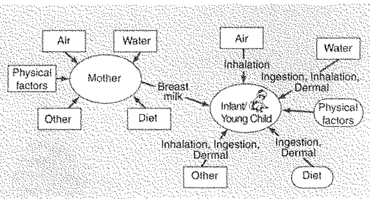
EPA has developed policies and guidance to consider children, but it has not maintained attention to children through agency strategies and priorities. In 1996, EPA created a national agenda on children's health, and its 1997 and 2000 strategic plans highlighted children's health as a key cross-agency program. As a result, the agency's research advanced the understanding of children's vulnerabilities. However, EPA has not updated the agenda since 1996, and the focus on children is absent from the 2003, 2006, and September 2009 draft strategic plans.

EPA has not fully used the Office of Children's Health Protection and other child-focused resources. The active involvement of managers from the office and experts from the Children's Health Protection Advisory Committee has been lacking, as has the involvement of key staff throughout EPA. Although EPA now has a new Director of Children's Health, the office had not had consistent leadership since 2002, hampering its ability to support and facilitate agencywide efforts and elevate matters of importance with senior officials. For example, a previous director established workgroups to bring together officials from the program offices and the children's health office, but a subsequent acting director eliminated these groups, effectively halting work on a key set of children's health recommendations. In addition, the regional children's health coordinators—who provide outreach and coordination for EPA—have no national strategy or dedicated resources. Finally, the advisory committee has provided hundreds of recommendations, but EPA has requested advice on draft regulations only three times in the last decade.

While EPA leadership is key to national efforts to protect children from environmental threats, EPA's efforts have been hampered by the expiration in 2005 of certain provisions in the executive order. For example, the Task Force on Children's Environmental Health provided EPA with a forum for interagency leadership on important federal efforts, such as the National Children's Study. It also provided biennial reports that helped establish federal research priorities.

Children Are Exposed to Many Sources of Potentially-harmful Environmental Pollutants

Infant/Young Child
Exposures for the infant and young child can occur through all environmental media. When breastfed, the mother's exposure to environmental media can be an additional source of exposure to the infant.



Source: EPA. A Framework For Assessing Health Risks of Environmental Exposure to Children (2006).

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Abbreviations

ACE	*America's Children and the Environment*
Advisory Committee	Children's Health Protection Advisory Committee
CDC	Centers for Disease Control and Prevention
EPA	Environmental Protection Agency
Executive Order	Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks
Healthy SEAT	Healthy Schools Environments Assessment Tool
Interagency Forum	Federal Interagency Forum on Child and Family Statistics
Miami Declaration	*Declaration of the Environmental Leaders of the Eight on Children's Environmental Health*
NAAQS	National Ambient Air Quality Standards
National Agenda	*National Agenda to Protect Children's Health from Environmental Threats*
Office of Children's Health	Office of Children's Health Protection
OMB	Office of Management and Budget
RAPIDS	Rule and Policy Information Development System
Task Force	Task Force on Environmental Health Risks and Safety Risks to Children

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GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

January 28, 2010

The Honorable Barbara Boxer
Chairman
Committee on Environment and Public Works
United States Senate

The Honorable Amy Klobuchar
Chairman
Subcommittee on Children's Health
Committee on Environment and Public Works
United States Senate

Children face disproportionate health risks from environmental contaminants such as pollution in air, lead paint in homes, pesticide residues on food, and treatment-resistant microbes in drinking water. Such hazards contribute to asthma, cancer, neurodevelopmental disorders, and other diseases, and many of the nation's 74 million children are exposed to them daily. In 2007, for example, 66 percent of children lived in counties where air exceeded one or more of the six principal pollutants.[1] Two of them—ozone and particulate matter—are known to cause or aggravate respiratory diseases such as asthma. According to the Centers for Disease Control and Prevention (CDC), asthma is the third most common cause of hospitalizations for children, resulting in $3.2 billion for treatment and 14 million days of school lost annually.

The environment's effect on children's health is complex, and scientists' understanding has continued to evolve. It can be challenging to assess the contribution of environmental exposures to childhood illnesses, because factors such as family history, nutrition, and socioeconomic factors also contribute. Nonetheless, scientists agree that children often are more significantly affected by environmental risks from exposure to air pollution, toxic chemicals, and the disease-transmitting vectors that are expected to increase with global warming. Research has also shown that childhood exposures to environmental contaminants may affect risk of diseases, such as cancer, later in life.

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[1] The Environmental Protection Agency sets National Ambient Air Quality Standards for ozone, particulate matter, sulfur dioxide, nitrogen dioxide, carbon monoxide, and lead.

In the late 1990s, the federal government took several steps to make children's environmental health a priority. In April 1997, the President signed Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks (Executive Order), which mandated a concerted federal effort to address children's environmental health and safety risks. The Executive Order established, among other things, an interagency Task Force on Environmental Health Risks and Safety Risks to Children (Task Force) and charged it with recommending strategies to the President for protecting children's health and safety. Also in 1997, the Environmental Protection Agency (EPA) created the Office of Children's Health Protection (Office of Children's Health) to support the agency's efforts and formed the Children's Health Protection Advisory Committee (Advisory Committee) to provide advice, information, and recommendations to assist the agency in the development of regulations, guidance, and policies relevant to children's health.[2]

EPA's Advisory Committee and the EPA Office of Inspector General have raised concerns about whether the agency has continued to maintain its earlier focus on protecting children or capitalized on opportunities to tackle some significant and emerging environmental health challenges. For example, the Advisory Committee wrote to the EPA Administrator in April 2007 to reflect on EPA's achievements in the 10 years since the Executive Order was signed. The committee cited successes such as increased margins of safety for pesticides mandated under the Food Quality Protection Act and the creation of the National Children's Study. However, the Advisory Committee also expressed serious concerns about EPA's continued lack of focus on children's environmental health issues and the lack of progress in addressing the committee's many recommendations. The EPA Inspector General had also raised many of those concerns in 2004.[3]

To address concerns about EPA's focus on children, you asked that we assess the agency's consideration of children's environmental health. In September 2008, we testified on our preliminary assessment of EPA's efforts to address children's environmental health, focusing on the

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[2] In 2005, EPA expanded the office to include environmental education and aging initiatives, renaming it the Office of Children's Health Protection and Environmental Education.

[3] EPA Office of Inspector General, *The Effectiveness of the Office of Children's Health Protection Cannot Yet Be Determined Quantitatively*, Report No. 2004-P-00016 (Washington, D.C., May 17, 2004).

Advisory Committee.[4] This report completes our work for you, addressing more broadly the extent to which EPA has institutionalized the protection of children's health from environmental risks through (1) agency priorities, strategies, and rulemakings, including implementation of Executive Order 13045; (2) the use of key offices and other child-focused resources, such as the Office of Children's Health and the Advisory Committee; and (3) involvement in federal interagency efforts to protect children from current and emerging environmental threats.

To address those objectives, we interviewed officials from multiple EPA program offices most directly involved with children's health issues and referred to long-established quality management criteria from the Government Performance and Results Act.[5] To assess the extent that EPA prioritized children's health in its agencywide strategies and goals, we reviewed key EPA children's health-related policies, strategic and performance plans, and guidance documents. To assess the implementation of the Executive Order through EPA's rulemaking process, we reviewed regulations subject to the regulatory requirements of the order, as well as internal workgroup documents detailing EPA's rulemaking—National Ambient Air Quality Standards for Particulate Matter—published in October 2006. To assess EPA's use of its Advisory Committee, we analyzed documents—including meeting agendas, letters from the Advisory Committee to the EPA Administrator, and EPA's response letters. To examine EPA's involvement in national children's health efforts, we identified the accomplishments of the Task Force that EPA co-chaired, and we reviewed reports from groups such as the Federal Interagency Forum on Child and Family Statistics (Interagency Forum). Appendix I provides a more detailed description of our scope and methodology. We conducted this performance audit from November 2008 through January 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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[4] GAO, *Environmental Health: EPA Efforts to Address Children's Health Issues Need Greater Focus, Direction, and Top-Level Commitment*, GAO-08-1155T (Washington, D.C.: Sept. 16, 2008).

[5] Pub. L. 103-62 (1993).

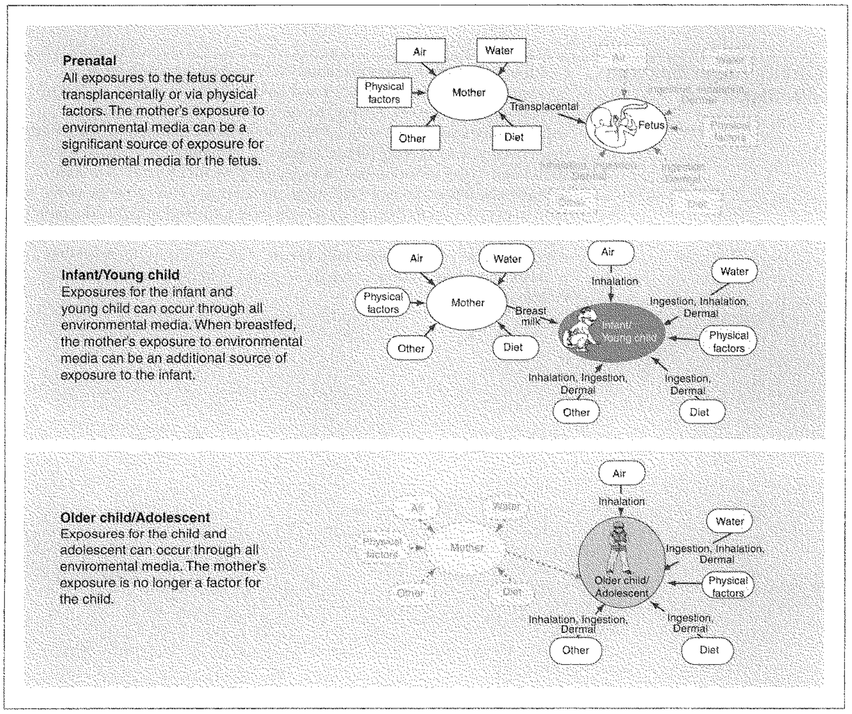
Background

The following section discusses issues related to children's environmental health risks and key actions that EPA, the President, and Congress took in the early 1990s to help address those risks.

Children's Environmental Health Risks

Children are often disproportionately affected by environmental contaminants, such as pesticides and lead, for many reasons, including greater exposure levels, unique exposure pathways, and greater vulnerability due to their still-developing bodies. For example, EPA noted that children may receive higher doses of contaminants, because they spend more time close to the ground; engage in more hand-to-mouth activities; and breathe more air, drink more water, and consume more food in proportion to their body weight than adults. Contaminants may also affect children disproportionately because of their unique exposure routes such as transplacental and breast milk. Figure 1 illustrates the relevant exposure routes during three major developmental periods of childhood.

Figure 1: Exposure Routes and Levels Change During Major Developmental Periods Of Childhood



Prenatal
All exposures to the fetus occur transplancentally or via physical factors. The mother's exposure to environmental media can be a significant source of exposure for enviromental media for the fetus.

Infant/Young child
Exposures for the infant and young child can occur through all environmental media. When breastfed, the mother's exposure to environmental media can be an additional source of exposure to the infant.

Older child/Adolescent
Exposures for the child and adolescent can occur through all enviromental media. The mother's exposure is no longer a factor for the child.

Source: EPA, A Framework For Assessing Health Risks of Envirnmental Exposure to Children (2006).

Note: Arrows represent exposure routes for a given developmental period, while shaded dashed lines represent exposure routes that are not pertinent for the period.

Children also are more vulnerable than adults because of the relative immaturity of their biochemical and physiological systems. For example, air pollutants that would produce only slight breathing difficulties in adults may contribute to a more serious breathing problem in young children because of their smaller airways. Finally, EPA has noted that children have limited ability to communicate and urge action about their environment, so others must act on their behalf.

In 1993, the National Academy of Sciences summarized the state of the science concerning the effects of environmental contaminants on children's health and helped institutionalize the idea that children are not "little adults."[6] That groundbreaking study outlined some of the profound differences between children and adults and was followed, in 1996, by congressional enactment of the Food Quality Protection Act, which mandated use of a 10-fold safety factor for children in setting pesticide residue tolerances.[7] Since the early 1990s, scientists have expanded our understanding of environmental health consequences beyond childhood diseases and disorders and began examining how childhood exposures affect people throughout all lifestages. The term lifestage refers to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and physiological characteristics that are associated with development and growth. EPA now views childhood as a sequence of lifestages from conception through fetal development, infancy, and adolescence, rather than considering children as a subpopulation.[8] In its 2005 *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants,* EPA recommended use of the following childhood age groups for assessing risk from environmental exposures:

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[6] National Research Council, National Academy of Sciences, *Pesticides in the Diets of Infants and Children* (Washington, D.C., 1993).

[7] The Food Quality Protection Act provisions allowed EPA to use a different safety factor if the Administrator finds that reliable data demonstrate it would be safe for infants and children. Pub. L. No. 104-170 § 405 (1996).

[8] The term "subpopulation" is ingrained into EPA's past practice, as well as various laws that EPA administers, such as the Safe Drinking Water Act Amendments (1996). Prior to the publication of the 2005 *Guidelines for Carcinogen Risk Assessment* and the 2005 *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants,* EPA described all types of groups of individuals as "subpopulations."

- age groups less than 12 months old include: birth to <1 month, 1 to <3 months, 3 to <6 months, and 6 to <12 months; and

- age groups greater than 12 months old include: 1 to <2 years, 2 to <3 years, 3 to <6 years, 6 to <11 years, 11 to <16 years, and 16 to <21 years.

According to EPA guidance, other lifestages, including pregnancy, nursing, and old age, may also be important to consider when assessing human exposure and health risk.

In addition to the growing awareness about the impact that childhood exposures may have on health risks throughout later lifestages, awareness has also grown about the linkage between children's environmental health and environmental justice issues such as health disparities seen in affected population groups. The Interagency Forum reported that the environmental health risks that disproportionately affect children are likely to disproportionately affect minority and low-income children because of demographic trends in the United States.[9] According to the U.S. Census Bureau, there were 73.9 million children ages 0 to 17 in the United States in 2008, 1.5 million more than in 2000. Although the number of children living in the United States has grown, the percentage of children has decreased steadily, from a peak of 36 percent at the end of the "baby boom" in the mid-1960s to a current 24 percent—where it is expected to remain through 2020. At the same time, the racial and ethnic composition of the country's children is expected to diversify.

EPA's Early Actions to Institutionalize Children's Environmental Health

EPA's mission is to protect human health and the environment and, as a result of mounting evidence about the special vulnerabilities of the developing fetus and child, the agency took actions to emphasize protection of children from environmental exposures. In 1995, EPA established an agencywide *Policy on Evaluating Health Risks to Children*, directing EPA staff to consistently and explicitly consider risks to infants and children as a part of risk assessments generated during its decision-making processes, and when setting standards to protect public health and the environment (see app. II). In 1996, EPA issued the National Agenda to Protect Children's Health from Environmental Threats (National Agenda) and expanded the agency's activities to specifically address risks for children, documenting EPA's plans to achieve the following seven goals:

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[9] Interagency Forum on Child and Family Statistics, *America's Children: Key National Indicators of Well-Being* (Washington, D.C., 2009).

1. Ensure that all standards set by EPA are protective of any heightened risks faced by children.
2. Develop a scientific research strategy focused on the gaps in knowledge regarding child-specific susceptibility and exposure to environmental pollutants.
3. Develop new, comprehensive policies to address cumulative and simultaneous exposures faced by children.
4. Expand community right-to-know allowing families to make informed choices concerning environmental exposures to their children.
5. Encourage parental responsibility for protecting their children from environmental health threats by providing them with basic information.
6. Encourage and expand educational efforts with health care providers and environmental professionals so they can identify, prevent, and reduce environmental health threats to children.
7. Provide the necessary funding to address children's environmental health as a top priority among relative health risks.

In 1997, EPA also established the Office of Children's Health, within the Office of the Administrator, to support and facilitate the agency's efforts to implement the National Agenda as well as the Executive Order. The office's mission is to "make the protection of children's health a fundamental goal of public health and environmental protection in the United States and around the world." The office is not directly responsible for implementing or overseeing any EPA programs and instead carries out its mission by supporting and facilitating the work of other EPA offices, raising awareness and educating the public, participating in agency workgroups, and providing grant money that serves to assist communities in expanding awareness about children's health issues. To inform its various initiatives related to children's health, EPA also established the Advisory Committee in 1997. Through the Committee, leading researchers, academics, health care providers, nongovernmental organizations, industry representatives, as well as state and local government representatives advise EPA on regulations, research, and communications issues important to children's health.

Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks

The President issued the Executive Order in April 1997, which established a broad policy for a concerted federal effort to address children's environmental health risks and safety risks.[10] The Executive Order required each federal agency to (1) make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children and (2) ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks (see app. III). The Executive Order has four other key provisions relating to regulatory requirements, interagency coordination and strategies, research coordination and integration, and tracking of children's health indicators. With regard to regulations, the Executive Order requires federal agencies to develop two pieces of information as part of the rulemaking process: (1) an evaluation of the environmental health or safety effects on children of the planned rule; and (2) an explanation of why the planned rule is preferable to other potentially effective and reasonably feasible alternatives considered by the agency. The requirements of the Executive Order are among many broadly applicable regulatory requirements established by statutes and executive orders with which agencies must generally comply when issuing rulemakings. Individual rulemakings only trigger the specific analytical and procedural requirements of the Executive Order if they fall within specified conditions or impact thresholds. The requirements of the Executive Order are triggered if a rulemaking is likely to result in a rule that (1) meets the economic impact threshold, such as by having an annual impact of $100 million or more, and (2) concerns an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.

Statutory Requirements to Consider Children's Environmental Health

In addition to the broad mandate in the Executive Order, EPA and the Agency for Toxic Substances and Disease Registry are directed by Congress to consider children or other vulnerable populations in several environmental statutes. Table 1 lists those statutes and their express provisions related to children's health.

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[10] 62 Fed. Reg. 19,885 (Apr. 21, 1997).

Table 1: Provisions in Selected Environmental Statutes Expressly Concerning Children or Other Susceptible Subgroups

Statute	Regulated activity	Extent to which statute explicitly requires special consideration of children or susceptible subgroups in decision making
Food Quality Protection Act 21 U.S.C. §§ 321, 331, 333, 342, 346a	Pesticide residues on raw and processed food	In establishing tolerances and exemptions, EPA must consider infant and children's exposure, susceptibility, and cumulative effect, and apply a 10-fold margin of safety (unless data support a different margin); ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and publish a specific determination of safety.[a] Also, factors to be considered include exposure and sensitivity of subgroups.[b]
Safe Drinking Water Act 42 U.S.C. §§ 300f-300j-18	Public drinking water	In selecting a maximum contaminant level, EPA must analyze the effects on groups such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk, and subject the analysis to public notice and comment.[c] In selecting unregulated contaminants for consideration of regulation, EPA must consider the effects on subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) at higher risk than the general population.[d]
Federal Insecticide, Fungicide and Rodenticide Act 7 U.S.C. §§ 136-136y	Pesticide registrations	If pesticide is for use on food, then as part of its registration and reregistration, a tolerance or exemption must be established or reviewed under FQPA; see above.[e] EPA is authorized to establish packaging standards for pesticides.[f]
Comprehensive Environmental Response, Compensation, and Liability Act 42 U.S.C. §§ 9601-9675	Hazardous waste sites	Under response authorities, health risk assessments conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) are to consider susceptibility of the community.[g] ATSDR is also directed to conduct medical monitoring of subgroups at risk.[h]
Resource Conservation and Recovery Act 42 U.S.C. §§ 6901-6992k	Hazardous waste handling, treatment, storage, disposal	In the context of hazardous waste landfill permits, where ATSDR is asked to do health assessments, the agency is to consider susceptibility of the community in conducting assessments.[i]

Source: GAO.

Note: Statutes were reviewed as amended, and are cited to the codification

[a] 21 U.S.C. § 346a(b)(2)(B)(vi), (C) (tolerances), (c)(2)(B) (exemptions). There are limited exceptions (e.g., use safer than nonuse; unavoidable residues).

[b] 21 U.S.C. § 346a(b)(2)(D)(vi), (vii).

[c] 42 U.S.C. § 300g-1(b)(3)(C)(i)(V).

[d] 42 U.S.C. § 300g-1(b)(1)(C).

[e] 7 U.S.C. §§ 136(bb), 136a(c)(5), 136a-1(g)(2)(E).

[f] 7 U.S.C. § 136w(c)(3).

[g] 42 U.S.C. § 9604(i)(6)(F).

[h] 42 U.S.C. § 9604(i)(9)(A).

[i] 42 U.S.C. § 6939a(f).

Other Key EPA Children's Environmental Health Protection Activities

In 1998, EPA helped establish eight Centers for Children's Environmental Health and Disease Prevention Research, with the long-range goal of understanding how environmental factors affect children's health and translating basic research findings into methods and interventions to prevent adverse health outcomes. The program is jointly funded by EPA, through its Science to Achieve Results grants program, and the National Institute of Environmental Health Sciences, with additional expertise and low-cost laboratory services provided by CDC.[11] The program is designed to foster research collaboration among basic, clinical, and behavioral scientists with participation from local communities.

In 1999, EPA—and the other members of the Task Force—explored the feasibility of a longitudinal cohort study of environmental effects on parents and children, and in 2000 Congress authorized the planning and implementation of the National Children's Study as part of the Children's Health Act of 2000.[12] The study is designed to examine the effects of environmental influences on the health and development of 100,000 children across the United States, following them from before birth until age 21, with the goal of improving the health and well-being of children. EPA is one of a consortium of federal partners currently leading the study that includes the U.S. Department of Health and Human Services' National Institute of Child Health and Human Development, National Institute of Environmental Health Sciences of the National Institutes of Health, and CDC.[13]

In 2000, EPA published *America's Children and the Environment* (ACE), a report that brought together quantitative information from a variety of sources to show trends in environmental risk factors related to the health and well-being of children in the United States. The ACE report provides trend information on levels of environmental contaminants in air, water, food, and soil; concentrations of contaminants measured in the bodies of mothers and children; and childhood diseases that may be influenced by environmental factors. In 2003, EPA published the second ACE report, adding data for additional years; new measures for important contaminants, exposures, and childhood illnesses; and analysis of those measures by children's race, ethnicity, and family income. Since 2006, EPA has periodically updated the report data on its Web site.[14] EPA is currently updating the ACE report's measures and developing new priority topics, and it intends to publish a new edition by the end of 2010.

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[11] http://www.epa.gov/ncer/childrenscenters.

[12] Pub. L. No. 106-310, § 1004 (2000).

[13] http://nationalchildrensstudy.gov.

EPA Strategic Plans—Goals and Performance Measures

EPA first recognized children's environmental health as a cross-agency program in its 1997 strategic plan and related annual performance plans, which are required by the Government Performance and Results Act. EPA's strategic plan defines its mission, goals, and means by which it will measure progress in addressing specific problems or challenges over the course of at least 5 years. It also describes specific results the agency aims to achieve, what actions the agency will take to realize those planned results, and how the agency will deal with current and foreseeable internal and external challenges that may hinder achieving results. An agency formulates its strategic plan with input from the Office of Management and Budget (OMB); Congress; the agency's personnel, partners, and stakeholders; and the public. EPA's strategic plan also serves a number of important management roles and functions related to achieving its mission, for example allowing agency leadership to establish and communicate priorities and direction through a strategic and unified vision. It also is the foundation of the agency's planning system, for instance providing direction for programmatic functions such as human resources and budgeting, and serves to increase leadership accountability.

EPA Action Development Process and Related Children's Guidance

EPA implements various environmental statutes in part through rulemakings, which are guided by its Action Development Process that helps the agency comply with legal requirements, executive orders, directives, agency guidance, and national policies. EPA finalized the current process in June 2004 to ensure that it uses quality information to support its actions and that scientific, economic, and policy issues are adequately addressed at the right stages in action development.[15] The process has five major stages, each of which involves multiple steps. In the first stage, EPA assigns the rulemaking to one of three tiers based on the required level of cross-agency interactions and the nature of the anticipated issues, including complexity, environmental and economic significance, and external interest. According to agency guidance, EPA assigns rulemakings that are based on a human risk assessment—including assessments of environmental health risks to children—to tier 1 or tier 2. In the second stage, EPA uses a standard process to develop the proposed regulation and supporting analyses. In the third stage, EPA submits a regulatory package to OMB and addresses OMB comments, when required to do so under Executive Order 12866.[16] In the fourth stage, EPA requests the Administrator's signature and publishes the draft regulation in the *Federal Register*. In the fifth stage, EPA develops the final action and facilitates Congressional review. In developing the final regulation, EPA repeats many of the steps it followed to develop the draft regulation. The final step in the process is to submit the final regulation to Congress and GAO.

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[14] EPA, *America's Children and the Environment*, http://www.epa.gov/economics/children (accessed Jan. 15, 2010).

[15] EPA, *EPA's Action Development Process: Guidance for EPA Staff on Developing Quality Actions* (Washington, D.C., 2004).

In October 2006, EPA's Office of Policy Economics and Innovation issued additional guidance to assist agency staff in integrating children's health considerations into the process.[17] The children's guidance describes provisions of the Executive Order and EPA's Policy on Evaluating Health Risks to Children. Figure 2 illustrates key steps in EPA's Action Development Process where children are to be considered by the agency.

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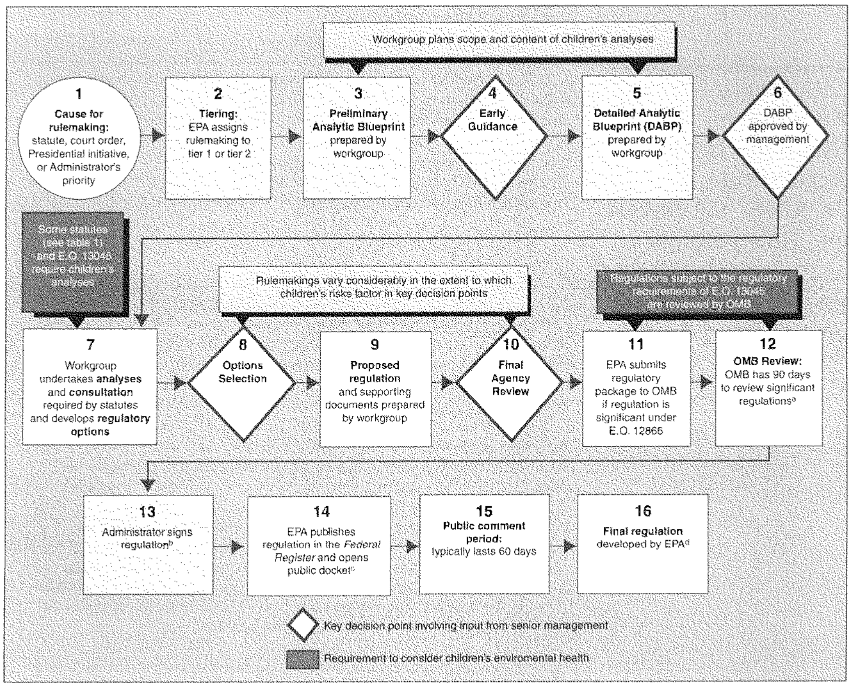
[16] Executive Order 12866 directs most agencies, including EPA, to, among other things, assess costs and benefits of available regulatory alternatives and to submit significant rules to OMB's Office of Information and Regulatory Affairs for review before they are published. 58 Fed. Reg. 51,735 (1993). For a summary of agencies' responsibilities for rulemakings under broadly applicable requirements, see app. I of GAO, *Federal Rulemaking: Improvements Needed to Monitoring and Evaluation of Rules Development as Well as to the Transparency of OMB's Regulatory Reviews*, GAO-09-205 (Washington, D.C.: Apr. 20, 2009).

[17] EPA, *EPA's Action Development Process: Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children* (Washington, D.C., 2006).

Figure 2: Steps Where Children Are Considered in the EPA Rulemaking Process


Workgroup plans scope and content of children's analyses
1
Cause for rulemaking: statute, court order, Presidential initiative, or Administrator's priority
2
Tiering: EPA assigns rulemaking to tier 1 or tier 2
3
Preliminary Analytic Blueprint prepared by workgroup
4
Early Guidance
5
Detailed Analytic Blueprint (DABP) prepared by workgroup
6
DABP approved by management
Some statutes (see table 1) and E.O. 13045 require children's analyses
Rulemakings vary considerably in the extent to which children's risks factor in key decision points
Regulations subject to the regulatory requirements of E.O. 13045 are reviewed by OMB
7
Workgroup undertakes analyses and consultation required by statutes and develops regulatory options
8
Options Selection
9
Proposed regulation and supporting documents prepared by workgroup
10
Final Agency Review
11
EPA submits regulatory package to OMB if regulation is significant under E.O. 12866
12
OMB Review: OMB has 90 days to review significant regulations[a]
13
Administrator signs regulation[b]
14
EPA publishes regulation in the Federal Register and opens public docket[c]
15
Public comment period: typically lasts 60 days
16
Final regulation developed by EPA[d]
◇ Key decision point involving input from senior management
▨ Requirement to consider children's enviromental health

Source: GAO analysis of EPA's Action Development Process.

[a] EPA may request a one-time 30-day extension.

[b] The Administrator may delegate signature authority to an Assistant or Associate Administrator or Regional Administrator.

[c] A docket can be established at any time during the rulemaking process, but should open no later than the date of publication in the *Federal Register*. A docket should contain all information relied upon by EPA in developing an action.

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[a] Developing the final regulation involves reconvening the workgroup to evaluate comments received on the proposal and determine the appropriate next steps for preparing the final action, which could range from repeating all of the steps as outlined in the process for preparing the proposal to only doing a subset of those steps.

EPA Has Not Focused Attention on Children's Health in Agencywide Priorities, Strategies, and Rulemakings

EPA has not updated the National Agenda since it issued the priority-setting document in 1996. EPA's 1997 and 2000 strategic plans included children as an explicit goal or program, but the agency's subsequent two plans showed a reduced emphasis on children. EPA has not systematically evaluated or tracked how its rulemakings addressed children's environmental health risks, and regulatory requirements in the Executive Order have had minimal impact on EPA rulemakings.

EPA Has Not Updated the National Agenda in More than a Decade

EPA has not updated the *National Agenda to Protect Children's Health from Environmental Threats* in more than 10 years. Issued in 1996, the National Agenda established children's environmental health as a top priority and a central focus of all agency efforts. In it, EPA articulated the agency's commitment to children's health by identifying an array of environmental threats to children and specifying a multifaceted approach to accomplishing its children's health goals. The National Agenda also was the impetus for the creation of EPA's Office of Children's Health, which was formed to support the agency's implementation of the National Agenda. These actions are consistent with our prior work on implementing change in the federal government, which has shown that top leadership must provide a clear, consistent rationale for change and develop a framework that helps create a new culture. Moreover, the National Agenda also helped to institutionalize the agency's commitment to the issue. According to current and former officials from the Office of Children's Health, the National Agenda and Executive Order helped legitimize the office's importance across the rest of the agency.

Several demonstrable children's health-focused activities were initiated shortly after the EPA Administrator who founded the Office of Children's Health issued the National Agenda (see table 2). For example, in 1999 the agency explored—through the Task Force—the feasibility of a longitudinal cohort study of environmental effects on parents and children, which Congress later established as the National Children's

Study.[18] In 2000, EPA issued a strategy for research on environmental risks to children that established EPA's long-term program goals and documented its rationale.[19] The National Agenda also asserted EPA's leadership across the federal government and called on partners in Congress, industry, health professions, and interest groups to adopt and help EPA implement these children's health priorities.

Table 2: Priorities From EPA's National Agenda and Examples of Related Actions

National Agenda priority	Children's environmental health action
1. Ensuring that EPA standards are protective of potentially heightened risks faced by children	• In 1997, EPA asked its Advisory Committee to recommend five existing standards that may merit re-evaluation. In 1999, EPA identified eight regulations and regulatory areas for review, including pesticide tolerances and farm worker protection standards. • In 1997, EPA set air standards for particulate matter and ozone to provide additional health protection to 35 million children and set standards for fine particulate matter for the first time. • In 1998, EPA published a final Guidance for Rule Writers to risk assessors and managers who are developing regulatory standards that are specifically targeted at pregnant women, infants, and children.
2. Identifying and expanding scientific research on child-specific susceptibility to environmental pollutants	• In 1998, EPA partnered with the National Institute of Environmental Health Sciences (NIEHS) to establish children's health research centers to promote research and intervention and prevention methods in order to better understand how environmental factors affect children's health. • In 1999, EPA helped to initiate what became the National Children's Study (see text above).
3. Developing policies addressing cumulative and simultaneous exposures	In 1997, EPA published cumulative risk assessment guidance that recommended the integration of multiple sources, effects, pathways, stressors, and populations in risk assessments for which relevant data are available, with emphasis on sensitive subgroups such as infants and children.
4. Expanding community right-to-know efforts	EPA expanded public access to agency information on pollution, particularly through the Internet, to help people prevent pollution in their neighborhoods and protect the health of a community's children. For instance, EPA developed a national listing of state fish consumption advisories to make the advisories more accessible.
5. Providing information to parents on environmental threats in homes, schools, and communities	In 1998, EPA began publication of a Children's Environmental Health Yearbook to be a resource guide of EPA activities for the public.

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[18] P.L. 106-310.

[19] The research strategy has not been updated since its publication. Instead, EPA integrated children's environmental health into its Office of Research and Development multiyear human health research plans.

National Agenda priority	Children's environmental health action
6. Educating health and environmental professionals to prevent and reduce threats to children	In 1998, EPA, in conjunction with the Agency for Toxic Substances and Disease Registry, established Pediatric Environmental Health Specialty Units to provide critical expertise to health care professionals, parents, schools, and community groups on protecting children from environmental hazards, as well as to work with federal, state, and local agencies to address children's environmental health issues in homes, schools, and communities.
7. Funding to address children's environmental health as a top priority among relative health risks	Since 1998, EPA and NIEHS share responsibility for funding the children's health research centers, with EPA providing half the funding through its Science to Achieve Results program.

Source: GAO analysis of EPA documents.

EPA officials with whom we spoke recognized the importance of the National Agenda for helping to institutionalize children's health as a priority across EPA, noting that it gave children's health more traction and consideration in EPA programs and activities. In its 2004 report, EPA's Inspector General stated that while EPA has taken steps toward meeting the goals outlined in the agenda, with programs and regional offices carrying out projects focused on children's environmental health, there was no overall, coordinated strategy to integrate the agency's efforts on behalf of children.[20] Moreover, as we have previously reported and testified, EPA took actions that directly contradicted a National Agenda priority in December 2006.[21] Specifically, the agency finalized a rulemaking that significantly reduced the amount of publicly available information reported to the Toxics Release Inventory about toxic chemicals released into air, water, and land. Ultimately, Congress acted to overturn EPA's actions.[22]

In the first few months of 2009, EPA's newly appointed Administrator recommitted the agency to helping ensure protection of children's environmental health, stating in a speech that children are a driving force behind the agency's priorities.[23] In July 2009, she appointed a new Director of the Office of Children's Health and said that the director will also serve as a key advisor in the Administrator's office. In order to develop concrete ways to implement the new commitment, the Administrator tasked the new director with developing recommendations to improve regulatory and nonregulatory consideration of children's environmental health across EPA. In September 2009, the new director outlined the following five-part approach to ensure protection of children's environmental health:

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[20] EPA Office of Inspector General, Report No. 2004-P-00016.

[21] GAO, *Environmental Information: EPA Actions Could Reduce the Availability of Environmental Information to the Public*, GAO-07-464T (Washington, D.C.: Feb. 6, 2007), and *Toxic Chemical Releases: EPA Actions Could Reduce Environmental Information Available to Many Communities*, GAO-08-128 (Washington, D.C.: Nov. 30, 2007).

[22] Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, § 425 (2009).

[23] Administrator Lisa P. Jackson, Remarks at the Columbia University Center for Children's Environmental Health, March 30, 2009.

- *Regulatory and policy development:* EPA will work to ensure that regulations—for example, National Ambient Air Quality Standards (NAAQS)—provide for protection of children's environmental health. It will also ensure that policies focus on health disparities among different demographic groups of children, and their causes.
- *Safe chemicals management:* EPA will ensure that children, and other susceptible populations such as the elderly, are considered in the context of chemicals management programs and implementation and potential reform of the Toxic Substances Control Act.[24]
- *Implementation of community-based children's health programs:* EPA will re-establish a pivotal and influential role in working with tribes, states, and local governments to design and implement policies that improve the environment and protect children.
- *Research and science policy:* EPA will work with internal and external researchers to fill critical gaps in the understanding of children's vulnerabilities, unique exposures, and health effects, and will apply science policies that appropriately reflect uncertainties in children's vulnerabilities in EPA risk assessments.
- *Measuring effectiveness of EPA programs:* EPA will update its report *America's Children and the Environment,* which brings together quantitative information from a variety of sources to show trends in levels of environmental contaminants and concentrations of contaminants in the bodies of mothers and children, among other things.

The director told us about some specific steps he plans to take within the Office of Children's Health as part of the approach, including shifting resources so that the office has more public health expertise and realigning the office's focus to support the development of regulations and child-specific programs. In addition, he said he was confident the Administrator would begin to make other changes related to children's health strategy, although he could not provide a time frame or specific actions the agency had planned to implement such changes. Nonetheless, the EPA Administrator has yet to formalize new priorities in a visible and public way that contains specific actions EPA intends to take, as it did in the National Agenda. In contrast, EPA has publicly committed to improvements in other areas, such as chemicals management for which the agency released in September 2009 a comprehensive approach to enhance the agency's chemical program.[25]

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[24] Pub. L. 94-469 (1976); codified as amended at 15 U.S.C. §§ 2601 et seq.

EPA Recent Strategic Plans Indicate a Reduced Emphasis on Children's Health

EPA identified children's health as a cross-agency program in its 1997 and 2000 strategic plans.[26] However, EPA's 2003 and 2006 (current) plans did not include children's health as an explicit goal or program, indicating that the agency has placed less emphasis on protecting children's health.[27] The plans' goals and measures are meant to make the key components of an organization's mission explicit, thereby guiding officials in how to carry out the mission. In keeping with the requirements of the Government Performance and Results Act, EPA issued strategic plans setting forth goals that reflected top Administrator priorities; the plans also discuss cross-agency programs that cut across traditional media and organizational boundaries to consider, with a more comprehensive view, the risks posed to particular or vulnerable populations. EPA officials said that the agency removed this cross-agency goal when it streamlined its strategic plan from a 10-goal to a 5-goal structure, which was done as a result of EPA and OMB priorities.[28] According to EPA officials, children are considered as part of the plans' Goal 4, Healthy Communities and Ecosystems. The staff from the Office of Children's Health told us they were not pleased with the change to a 5-goal structure, because the subsequent strategic plans no longer emphasized children's environmental health. In addition, the office had previously developed its own draft strategic plan that included a range of children's health performance measures and demonstrated how such measures fit within EPA's overall strategic plan. However, that work was not incorporated into, or referenced by, the agencywide strategic plan, in part, because the office had limited involvement in EPA's strategic planning process.

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[25] In September 2009, the EPA Administrator announced a five-part comprehensive approach to enhance chemical management under existing laws. This approach includes developing chemical action plans, which should target the agency's risk management efforts on chemicals of concern, and increasing public access to information about chemicals.

[26] The Government Performance and Results Act requires that each agency prepare a strategic plan that defines its missions, goals, and the means by which it will measure its progress over a 5-year period and update them every 3 years. For example, EPA's 1997 plan covered years 1997 through 2001.

[27] EPA has issued four strategic plans since 1997, and is currently in the process of issuing its 2009-2013 plan.

[28] EPA's 2003 and 2006 strategic plans include five goals: (1) Clean Air and Global Climate Change, (2) Clean and Safe Water, (3) Land Preservation and Restoration, (4) Healthy Communities and Ecosystems, and (5) Compliance and Environmental Stewardship.

To help develop EPA's 2009 strategic plan, the agency held meetings in 2008 and 2009 to identify target areas for improvement. In the latest draft of that plan that EPA provided to us, the agency identified target areas for improvement—significant changes in strategy or performance measurement that are critical for helping the agency achieve and measure environmental and human health outcomes.[20] We found that children's health was not included as a target area in the draft strategic plan, and it is not yet clear to what extent children's health will be addressed in the final plan, which is subject to revision before the Administrator finalizes it in the coming months. We also found that the Office of Children's Health was not a lead office for developing the plan's goal for Healthy Communities and Ecosystems. Development of this goal has been co-led by EPA's Office of Prevention, Pesticides and Toxic Substances; Office of Research and Development; and Office of Water. EPA planning officials told us that staff from the Office of Children's Health attended at least one development meeting for the healthy community goal. However, the office staff said their input was not given much weight, since three other offices were assigned the leadership role for coordinating the goal's team. EPA officials said that a possible reason the Office of Children's Health did not become central to the process was that it is not directly responsible for implementing or overseeing any of the programs and subobjectives under the Healthy Communities and Ecosystems goal.

We recognize that EPA's strategic plan addresses five high-level goals and related objectives that generally relate to major media goals such as improving water quality or reducing chemical risks. Therefore, the strategic plans contain subobjectives and strategic targets that provide a higher degree of specificity and allow EPA to more clearly express priorities. However, our analysis of EPA's last two strategic plans found few subobjectives or strategic targets that explicitly related to children's health.[30] We have previously reported on the need for a strategic planning framework to contain critical elements such as performance goals that are indicative of agency priorities and also are objective, quantifiable, and measurable; an estimate of resources needed to meet performance goals; and an evaluation plan that monitors the goals.[31] EPA stated in its 2006 strategic plan that the agency directs its efforts toward the greatest threats in communities and the most sensitive populations, including children, who may be disproportionately exposed to environmental hazards. We found that only 2 of the 45 subobjectives relate specifically to children's environmental health: (1) asthma and (2) indoor air quality at schools.[32] We also found that, of the plan's 126 strategic targets, only 3 explicitly reference children or related issues: (1) reducing the percentage of women of childbearing age exposed to mercury, (2) eliminating lead poisoning, and (3) reducing blood lead levels.

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[20] The draft September 2009 strategic plan includes target areas for improvement, such as impacts of sustainable agriculture, global climate change, import safety, and environmental indicators.

With regard to the draft 2009 strategic plan that EPA planning officials provided us, 5 subobjectives (out of a total of 62) specifically address children's environmental health—reducing (1) exposure to asthma triggers, (2) indoor air contaminants at schools, (3) the percentage of women of childbearing age with mercury blood levels above safe thresholds, (4) blood lead levels in children, and (5) pregnant women's exposure to persistent organic pollutants.

Furthermore, regarding EPA's draft 2009 strategic plan, we found that the performance measures do not clearly measure children's health progress or are not explicitly linked to children's health objectives. Performance measures are indicators, statistics, or metrics used to gauge program performance. Reliable and comprehensive performance measures allow the agency to judge whether its performance targets are reasonable and whether it is meeting them. Moreover, as we have previously reported, strategic plans need to demonstrate that crosscutting programs—such as those for protecting children's environmental health—use the same performance measures across the offices implementing the programs. Our analysis indicates that 4 of the 12 performance measures (associated with the five subobjectives EPA identified) explicitly consider children, and only one of them measures a health outcome—the number of children ages 1 to 5 with elevated blood lead levels. The other 11 measures either did not directly measure children's health outcomes or were indirect proxy measures. We also found that for half of the 12 performance measures, the data or the data sources had inherent limitations. For example, the data source supporting the measure for "taking all essential actions to reduce exposure to indoor environmental asthma triggers" does not cover half of EPA's target population—children from birth to 3 years old—the age group most susceptible to health effects from secondhand tobacco smoke, a key asthma trigger according to CDC. EPA officials acknowledged that the data gaps for some performance measures are due a variety of reasons, including funding limitations. They added that EPA cannot necessarily guarantee availability of all the data used to support its performance measures, some of which are provided by other agencies.

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[30] OMB defines strategic targets as quantifiable or otherwise measurable characteristics that tell how well or at what level a program aspires to perform. Each subobjective typically has between one and four strategic targets.

[31] GAO, *Depot Maintenance: Improved Strategic Planning Needed to Ensure That Army and Marine Corps Depots Can Meet Future Maintenance Requirements*, GAO-09-865 (Washington, D.C.: Sept. 17, 2009).

[32] OMB defines objectives and subobjectives as statements of aim or purpose included in a strategic plan, required under the Government Performance and Results Act. EPA's current strategic plan has 9 subobjectives under goal 1, 5 subobjectives under goals 2 and 3, 20 subobjectives under goal 4, and 6 subobjectives under goal 5.

In contrast to the EPA's agencywide strategic plans, its Office of Research and Development has consistently addressed children's environmental health in its research plans. For example, working with other program offices, the office has addressed children's health in some of its multiyear research plans, which guide the direction of research over 5 or more years. The office develops separate multiyear plans on a variety of issues, including clean air, endocrine disruptors, human health risk assessments,[33] and human health research. The Office of Research and Development uses these multiyear plans to link its Annual Performance Plan, required under the Government Performance and Results Act, to longer-range objectives contained in EPA's strategic plan. In addition to these regular planning efforts, the Office of Research and Development has also developed strategies for addressing complex, cross-cutting programs, such as children's health. For example, the office published a *Human Health Research Strategy* in September 2003. Officials from the Office of Research and Development told us that the office is considering updating its August 2000 *Strategy for Research on Environmental Risks to*

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[33] Risk assessment is the process EPA uses to determine the nature and magnitude of health risks to humans from chemical contaminants and other stressors.

Children, and has held preliminary discussions with the Office of Children's Health.

The Office of Research and Development's *Human Health Research Program Multi-Year Plan* is EPA's primary research plan for addressing children's health, according to office officials. The plan supports the office's human health research program, which also provides methods to help reduce uncertainty in EPA's children's risk assessments, among other things. In June 2006, the office published an updated human health research plan for the years 2006 through 2013. The plan is organized according to the program's four long-term goals and explicitly addresses children's health in two of them. For example, children's health is addressed in the goal to ensure that "risk assessors and risk managers use the office's methods, models, and data to characterize and provide adequate protection for susceptible subpopulations." The plan considers children's health in all three of the research tracks supporting that goal—lifestages, methods for longitudinal research, and research on asthma.[34] In fact, a generally positive review of the research plan by EPA's Board of Scientific Counselors—which the agency established to provide advice, information, and recommendations about its research program—found that EPA may be overemphasizing children in its research on susceptible subpopulations. The board recommended in its December 2009 report that EPA redress research program imbalances within the lifestage arm to match the strengths of its childhood susceptibility research thrust with an expanded research program addressing subgroups across the entire age range, including the elderly.[35]

EPA Has Not Evaluated or Consistently Documented How Its Rulemakings Address Risks to Children

EPA's 1995 policy directs the agency to consider the risks to infants and children consistently and explicitly as part of risk assessments—including those used to support rulemakings—or state clearly why it did not. EPA cannot be assured that it has thoroughly addressed risks to children, because it lacks a system for evaluating and documenting how the agency has considered them in rulemakings. We identified three examples. First, EPA implements the Executive Order, in part, through its efforts to institutionalize its 1995 policy. However, EPA has not evaluated the extent to which its risk assessments conform to this policy.[36] Officials from the Office of Children's Health told us that significant information gaps remain concerning children's risks. Second, EPA does not require rule writers to thoroughly document consideration of children in the agency's Rule and Policy Information Development System (RAPIDS). EPA uses RAPIDS to track, approve, and report on agency actions, including rulemakings. RAPIDS allows EPA staff to document milestones in all phases of the rulemaking process and archives key information, according to EPA. However, RAPIDS captures limited information about human health or children's environmental health considerations. It does not, for example, capture whether a risk assessment is conducted as part of a rulemaking. Furthermore, in January 2008, EPA eliminated a check-box in RAPIDS that indicated whether a rulemaking involved environmental health risks or safety risks that may pose disproportionate risks to children. EPA added three questions about human health impacts to RAPIDS, but those do not directly address disproportionate risks to children. In addition, the human health data maintained in RAPIDS can be inaccurate or incomplete because they are gathered early in the rulemaking process and are rarely updated later in the process, according to officials with whom we spoke. Finally, EPA does not require rule writers to document consideration of children in preambles of all published regulations, even though the Office of Children's Health has urged EPA to require this.

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[34] EPA's Web site explains its lifestages research (see http://www.epa.gov/nerl/goals/health/lifestage.html).

[35] EPA, Board of Scientific Counselors, *Review of the Office of Research and Development's Human Health Research Program at the U.S. Environmental Protection Agency* (Washington, D.C., 2009).

EPA has taken steps to comply with the Executive Order's requirements by, for example, publishing updated guidance to assist rule writers in addressing children's risks in October 2006.[37] The guidance identifies key steps where rule writers should consider children in the rulemaking process. For example, it advises workgroups that are developing a regulation to describe proposed children's analyses in their plans for data collection and analyses. The guidance also advises rule writers to work with risk assessors early in the rulemaking process to begin accumulating information about potential children's risks. EPA has also developed a variety of guidance to assist risk assessors in addressing risks to children, including 2005 guidance on assessing susceptibility from early life exposure to carcinogens and 2008 guidance on assessing children's exposures to environmental contaminants.[38] EPA's first use of the cancer guidance is its draft risk assessment for ethylene oxide—used to make antifreeze, detergents, and polyester, and as a fumigant pesticide. The draft assessment also includes EPA's first use—apart from pesticide tolerances—of an additional safety factor for children and proposes reducing the agency's 1985 standard of 3.6 parts per billion for protecting against cancer risks to a much stricter limit of 0.6 parts per trillion.

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[36] EPA's Office of Pesticide Programs noted that, as a result of the Food Quality Protection Act of 1996, its risk assessments routinely discuss the risks to infants and children resulting from use of pesticides.

[37] EPA, Office of Policy, Economics, and Innovation, *EPA's Action Development Process: Guide to Considering Children's Health When Developing EPA Actions: Implementing Executive Order 13045 and EPA's Policy on Evaluating Health Risks to Children* (Washington, D.C., 2006). This guide superseded *EPA's Rule Writer's Guide to Executive Order 13045* (Washington, D.C., 1998).

According to staff from the Office of Children's Health, some EPA staff are more aware than others of the need to consider children's risks in rulemakings, in part because of the guidance they helped develop. However, officials from the office told us that EPA has not taken additional steps that would help institutionalize the use of the applicable guidance. For example, EPA does not provide rule writers with specific training on the guidance, according to officials. Rule writers are required to attend a 3-day comprehensive training course organized by EPA's Office of Policy, Economics, and Innovation, but the course includes only a limited discussion of children's environmental health because of competing demands. The Office of Children's Health has instructed part of this course in the past, but has not done so since 2006, according to office officials. In addition, EPA has been slow to implement at least one guidance document aimed at improving consideration of children in risk assessments and economic analyses used to support rulemakings. Specifically, in 2005 EPA issued guidance on selecting age groups for monitoring and assessing childhood exposures to environmental contaminants, but did not use the guidance in developing a risk assessment until 2008.[39] In another example, EPA's Office of Policy, Economics, and Innovation issued guidance on assessing the economic value of children's health benefits in October 2003, but the Director of the

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[38] EPA, Risk Assessment Forum, *Supplemental Guidance for Assessing Susceptibility from Early Life Exposure to Carcinogens* (Washington, D.C., 2005). EPA, Office of Research and Development, *Child-Specific Exposure Factors Handbook* (Washington, D.C., 2008).

[39] EPA, Risk Assessment Forum, *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (Washington, D.C., 2005).

Office of Children's Health told us the agency could expand efforts to ensure that children are adequately considered in economic assessments.[40]

Although the Office of Children's Health can advocate that EPA address disproportionate risks to children, we found that it has had a limited role in rulemakings for a number of reasons. Because the office is not a regulatory office like the Office of Air and Radiation, it does not initiate rulemakings. Instead, the Office of Children's Health participates on regulatory workgroups as staff resources permit. Regulatory workgroups, which develop regulations, consist of members from EPA's program offices and regional offices. EPA does not maintain reliable information on the number of regulatory workgroups that have included a representative from the Office of Children's Health, but the office has participated on only a small number of regulatory workgroups because of its limited resources, according to office officials. They told us that from 2007 through 2008, the office participated in final review for seven rulemakings, including reviews of the NAAQS for ozone and lead.[41] The Office of Children's Health's limited resources may also have limited its participation on the regulatory workgroup responsible for EPA's most recently completed review of *National Ambient Air Quality Standards for Particulate Matter*, published in October 2006. The office's representative on the workgroup was not designated an official workgroup member who would receive all chapters of the draft regulation, according to internal documents that we reviewed. Furthermore, the office did not send a representative to two key meetings, according to the workgroup chairman. The office's current director told us that he views this as a critical part of the office's work, and he will increase its participation in EPA rulemakings.

EPA's rulemaking for particulate matter standards provides an illustration of a rulemaking in which EPA documented its efforts to comply with the Executive Order. For its air quality standards for particulate matter, EPA addressed children's risks throughout the rulemaking process, according to documents and EPA officials who served on the regulatory workgroup. For example, it considered children in quantitative and qualitative risk assessments and its analysis of the scientific bases for alternative policy options.[42] In addition, EPA addressed children's risks in internal documents, including briefing slides and documents for the rulemaking that we reviewed. The Administrator eventually selected standards that were less stringent than those recommended by the Office of Children's Health and by EPA advisory committees. EPA documented its analyses in the notices of the proposed and final regulations as well as in the public docket, and the United States Court of Appeals for the District of Columbia used these analyses, in part, to support its February 2009 decision to remand a key standard to EPA for review.[43] The court stated that EPA had failed to explain why it believed the standard would provide an adequate margin of safety against illness in children and other vulnerable subpopulations, as required by the Clean Air Act.[44] In its opinion, the court cited analyses by EPA staff and determined that the Administrator had apparently too hastily discounted studies of the effect of particulate matter on children.

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[40] EPA, Office of Children's Health Protection and Office of Policy, Economics, and Innovation, *Children's Health Valuation Handbook* (Washington, D.C., 2003).

[41] According to the Office of Policy, Economics, and Innovation, the agency conducted final review for 58 tier 1 or tier 2 regulations from 2007 through 2008.

Regulatory Requirements in the Executive Order Have Had Minimal Impact on EPA Rulemakings

The Executive Order requires EPA to evaluate the environmental health or safety effects on children of each of the covered regulations. However, the requirements had a minimal impact on rulemakings conducted between 1998 and 2008[45] for three reasons: (1) the order applied to a narrow subset of rulemakings, (2) EPA was already considering risks to children in the rulemaking process when the order took effect, and (3) EPA does not interpret the order as requiring any particular analyses on children's environmental health. Furthermore, we reviewed the preambles of all proposed and final regulations that EPA determined to be subject to the requirements, and found that EPA varied in how explicitly it addressed the requirements of the Executive Order therein.

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[42] EPA's Office of Research and Development was responsible for supporting much of the relevant research on particulate matter. More than 40 percent of the research citations in the Criteria Document and the Staff Paper, key documents prepared during the action development process then in effect, were supported by the office, according to EPA (see fig. 2).

[43] *American Farm Bureau Federation v. EPA*, 559 F. 3d 512, 519 (2009).

[44] Codified as amended at 42 U.S.C. Ch. 85 (2009).

[45] The Executive Order applies to rulemakings that are initiated after April 21, 1997, or for which a Notice of Proposed Rulemaking is published after April 21, 1998. EPA did not determine that any proposed or final regulations published before 1998 were subject to the order.

First, the Executive Order only applies to a narrow subset of regulations. We determined that just 17 EPA rulemakings were subject to the order since it took effect. On average, EPA applied the order to fewer than 2 of the approximately 450 rulemakings it completed each year, even though some of those rulemakings were especially important to children's health. One reason for the low number is that the order extends only to situations in which analysis of the regulation's effects on children has the potential to influence the regulation, according to EPA's interpretation. Thus, EPA does not apply the order to regulations that are based solely on technology performance, since health-based information cannot influence such regulations. EPA guidance states that the agency may be statutorily precluded from considering health or safety risks when setting certain technology-based standards. For example, under the Clean Air Act, EPA is required to base certain initial performance standards on emissions levels that are already being achieved by better-controlled and lower-emitting sources in an industry, and not on human health outcomes. On this basis, EPA determined that a proposed technology-based regulation on mercury emissions from cement plants, issued in May 2009, was not subject to the order, even though the regulation addressed an environmental health risk that disproportionately affects children's health.[46]

Another reason the Executive Order only applies to a narrow subset of regulations is that it applies only to rulemakings that are considered economically significant under a separate executive order—Executive Order 12866. As a result, individual EPA rulemakings only trigger the Executive Order's analytical and procedural requirements if they have an annual impact of $100 million or more, or will have certain material adverse economic effects, a criterion that excludes most of EPA's regulations. This is consistent with our 2009 report that stated most major rulemakings triggered the analytical requirements of the Regulatory Flexibility Act, Executive Order 12866, and the Paperwork Reduction Act but few other commonly applicable rulemaking requirements such as Executive Order 13045.[47] Between 1998 and 2008, EPA issued only 54 final regulations that were determined to be economically significant.[48]

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[46] *National Emission Standards for Hazardous Air Pollutants from the Portland Cement Manufacturing Industry Proposed Rule*, 74 Fed. Reg. 21,136, 21,170 (May 6, 2009).

[47] GAO-09-205.

[48] Executive Order 12866 also applies to "significant" rulemakings that meet criteria other than economic significance; however, Executive Order 13045's regulatory requirements are triggered only by economic significance.

According to a 2008 study—authored by staff from the Office of Children's Health—at least 65 regulations involving disproportionate risks to children were not subject to the Executive Order because they were not considered economically significant.[49] Fifty of those 65 regulations concerned the amount of pesticides that may remain in or on food. However, for those 50 rulemakings and the others that were not subject to the Executive Order, EPA must still comply with provisions in environmental statutes, such as the Food Quality Protection Act of 1996,[50] that expressly concern children (see table 1). Although the scope of the Executive Order's regulatory requirement is limited, EPA did apply it to some regulations that the agency estimated to significantly impact children's environmental health. For example, it applied to three rulemakings that established the NAAQS. According to the Director of EPA's Office of Children's Health, those standards are among the most important decisions EPA made regarding children's health.

A second reason that the Executive Order had a minimal impact on rulemakings is because EPA was already considering risks to children in its rulemaking process when the order took effect. For example, EPA's 1995 *Policy on Evaluating Health Risks to Children* directs agency staff to consider the risks to infants and children consistently and explicitly in all risk assessments, including those that support rulemakings. Another reason is that federal agencies were already required to perform some of the analyses that the order calls for. For example, both the children's executive order and Executive Order 12866, issued in 1993, require agencies to explain why a planned regulation is preferable to other "potentially effective and reasonably feasible alternatives" considered by the agency.[51] According to EPA officials, the agency does not provide additional documents to the Office of Information and Regulatory Affairs if a proposed regulation is subject to both the children's executive order and Executive Order 12866, rather than Executive Order 12866 alone. Nor has the Office of Information and Regulatory Affairs requested additional information about children's environmental health in these situations, according to officials from that office.

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[49] D. Payne-Sturges and D. Kemp, "Ten Years of Addressing Children's Health through Regulatory Policy at the U.S. Environmental Protection Agency." *Environmental Health Perspectives*, vol. 116, no. 12 (2008). The study covered the period from April 1998 to December 2006.

[50] Pub. L. No. 104-170, § 405 amended the standard-setting provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

[51] Executive Order 12866 of September 30, 1993, was amended by Executive Order 13258 of February 26, 2002, and Executive Order 13422 of January 18, 2007, and is still in effect.

Third, EPA does not require any particular analyses to comply with the Executive Order's mandate that agencies evaluate the effects of any planned regulation on children. EPA has guidance to assist staff in complying with this requirement, but it gives staff considerable discretion. Furthermore, past guidance has been inconsistent. For example, the agency's 2003 Children's Health Valuation Handbook notes that one way to address the requirement is to analyze the costs, benefits, or other economic impacts of a policy on a specific subpopulation. EPA's 2000 *Guidelines for Preparing Economic Analyses*, however, states that the Executive Order primarily addresses risks rather than economic analyses.

Furthermore, we found that EPA varied in how explicitly it addressed the requirements of the Executive Order in publication of regulations. Every EPA *Federal Register* notice of a regulation subject to the order has a section in the preamble specifically addressing the order. We reviewed this section of all relevant notices from 1998 through 2008, and EPA did not always provide information on how it complied with the Executive Order or on what it found in conducting the required analyses.[52] We found that EPA has not consistently documented in this section how it considered children's environmental health risks. Specifically, we found that EPA either quantified the effects on children or explained why it did not, or could not do so, for only 4 of the 17 of the rulemakings. We also found variation in the extent to which EPA provided information in the *Federal Register* notice about how the agency addressed the Executive Order's requirement to evaluate the environmental health or safety effects on children, with some notices providing minimal information. For example, the notices of the final regulations establishing the NAAQS for lead, ozone, and particulate matter merely stated that the standards may be especially important for children because the contaminants in question may disproportionately affect children's health. While EPA had conducted analyses of children's health in developing those regulations, this section of the notice did not provide the public with a summary of EPA's analyses, making it difficult for the public to understand the basis upon which EPA made its decision. Finally, EPA did not include, in the section on the Executive Order, any explanation of why a planned regulation is preferable to other "potentially effective and reasonably feasible alternatives" in 9 of 17 rulemakings. Appendix IV provides details of our analysis of EPA *Federal Register* notices for the 17 rulemakings that we determined to be subject to the Executive Order's regulatory requirements.

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[52] Unless otherwise noted, when we refer to *Federal Register* notices in this section, we are referring to the preamble section on Executive Order 13045. The Executive Order requires that, for covered actions, the agency conduct and submit these analyses to OMB. The analyses must also be made part of the administrative record or otherwise made available to the public, to the extent permitted by law. The Executive Order does not require that the *Federal Register* notices for such regulations explain the agency's analyses.

In some cases, EPA's preamble discussion of its compliance with the Executive Order went beyond identifying its requirements, while at least one other agency responsible for rules potentially concerning risks to children does not routinely address the order in its *Federal Register* notices of regulations. For example, some EPA notices included information on data gaps that limited EPA's ability to more fully address the order's requirements. In the notice for the *National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment* rule, EPA stated that data were not adequate to conduct a quantitative risk assessment specifically for children and that EPA assumed the same risk for children as for the population as a whole when evaluating regulatory alternatives. In contrast, the Food and Drug Administration does not appear to have discussed the Executive Order in its notices. This includes its notice on the final regulation—*Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation*—issued in July 2009, even though the regulation was economically significant and concerned a risk that disproportionately affects children.

In Recent Years, EPA Has Not Fully Utilized Its Office of Children's Health and Other Child-Focused Resources

EPA's Office of Children's Health has recently had inconsistent leadership and direction, and the agency has not fully utilized other child-focused resources, such as its regional children's health coordinators and its Advisory Committee.

EPA's Children's Health Protection Office Has Lacked Committed and Consistent Leadership

EPA's Office of Children's Health experienced multiple changes in leadership over the last several years, impairing its ability to fulfill its priorities and commitments. From 2002 to 2008, the office had four acting directors and no permanent director.[53] EPA staff told us the Office of Children's Health had difficulty maintaining focus because of the varied priorities and initiatives of each director. For example, in 2007, the acting director tasked office staff to form workgroups and collaborate with senior program office staff across the agency in response to a set of recommendations from the Advisory Committee. The committee had recommended expanding research and committing additional EPA infrastructure to children's health, among other things, and the Administrator and acting director had committed to addressing the recommendations. The office's subsequent acting director eliminated the workgroups, and the office has yet to meaningfully address the Advisory Committee's recommendations. The committee has previously noted leadership challenges in the office, writing in a December 2002 memo to the Administrator that the office could not continue to play a key role within EPA and across the nation without permanent leadership. In May 2004, EPA's Inspector General reported that the lack of a permanent director may have a negative impact on the longevity and importance of the children's environmental health program within EPA.[54]

We have previously reported that career government officials in leadership positions can help provide the long-term focus needed to institutionalize reforms that political appointees' often more limited tenure does not permit.[55] Committed and consistent leadership is particularly important to the Office of Children's Health. Its mission is broad and far reaching, requiring continuous integration and communication with other EPA offices. For example, the office participates frequently in agencywide workgroups such as the Science Policy Council and the Risk Assessment Forum. The office also contributes expertise on science issues within EPA. For instance, it works with agency scientists on how to consider age-specific biological differences when conducting exposure and quantitative risk assessments. Leadership is also important because the office is supported by few resources and has a small number of staff, and because responsibility for implementing agencywide children's health priorities ultimately resides with EPA's program and regional offices. These conditions necessitate a proactive leader who can secure commitments from other parts of EPA to develop children-focused cross-agency activities.

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[53] The first Director of the Office of Children's Health served almost 5 years, from 1997 through 2002. The four subsequent acting directors, from 2002 to 2008, served an average of 2 years.

[54] EPA Office of Inspector General, *The Effectiveness of the Office of Children's Health Protection Cannot Yet Be Determined Quantitatively*, Report No. 2004-P-00016 (Washington, D.C.: May 17, 2004).

[55] GAO, *Management Reform: Elements of Successful Improvement Initiatives*, GAO/T-GGD-00-26 (Washington, D.C.: Oct. 15, 1999).

We also found that the effectiveness of the Office of Children's Health has declined in the absence of direct and meaningful support from EPA's Administrator. In our report, we wrote that sustained top leadership commitment is the single most important element in successfully implementing organizational change and that this commitment is most prominently shown through personal involvement of top leaders in developing and directing reform efforts.[56] In 1997, EPA's then-Administrator provided the first director of the Office of Children's Health with the necessary support to pursue initiatives by, for example, endorsing the director's decision to review the extent to which children's environmental health was considered in EPA's research budget and regulatory and science policies. EPA staff told us that the Administrator also endorsed the office's work with the Office of Research and Development to incorporate children's health concerns into the agency's exposure assessment guidelines, cancer guidelines, and its database on chemical risks. In carrying out these initiatives, the former director had frequent contact with the Administrator, and was invited to all Administrator staff meetings, usually attending two each week. At these meetings, the director had the opportunity to speak directly with the Administrator's chief of staff and other EPA political appointees on children's health issues. Between 2001 and 2003, EPA's subsequent Administrator maintained a similar level of support for the director of the Office of Children's Health. For example, the Administrator gave the director significant responsibility for representing EPA at international children's health conferences. According to three former directors of the office, from 2003 until the 2009 installation of the new permanent director of the Office of Children's Health, the office directors have not been given high-profile responsibility for representing the agency. Furthermore, they have not had the same level of access to the Administrator, having no longer been invited to the Administrator's staff meetings. The current director recently told us that, while he does not attend the Administrator's regular senior-level meetings (i.e., with the assistant and regional administrators), he believes he has had the level of access to the Administrator that he needs.

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[56] GAO, *Diversity Management: Expert-Identified Leading Practices and Agency Examples*, GAO-05-90 (Washington, D.C.: Jan. 14, 2005).

EPA's Regions Have Widely Differing Staff Resources for Children's Health and Lack Leadership from Headquarters

EPA's 10 regional offices have widely differing staff resources dedicated to children's environmental health, because the regional administrators make that determination. As shown in figure 3, each region has a designated children's environmental health coordinator, but not every region has a full-time coordinator. Four regions have one-fifth of a staff position or less dedicated to children's health work.[57] Moreover, Region 6 and Region 9—together covering the states along the U.S. southern border—have one-hundredths of a staff position for children's environmental health. EPA's regional children's environmental health coordinators told us they believe they are often understaffed, and even the full-time coordinators are increasingly being asked to perform additional work not related specifically to children's health. As a result, they are not able to fully dedicate themselves to children's health.

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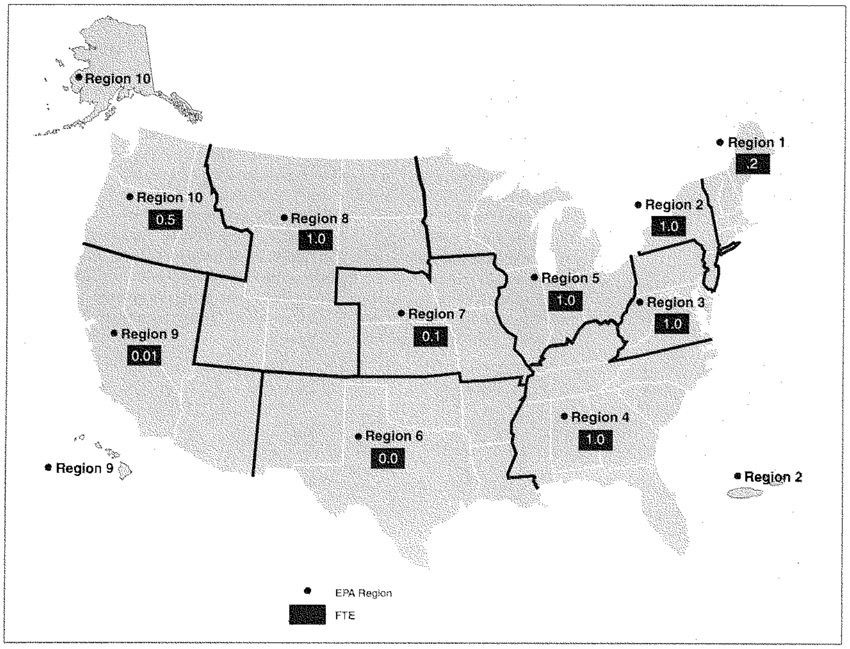
[57] Staff positions are measured in full-time-equivalents (FTE), which generally consists of one or more employed individuals who collectively complete 2,080 work hours in a given year. For example, one FTE can represent either one full-time employee or two half-time employees.

Figure 3: EPA Regional Children's Environmental Health Coordinator Staffing Levels by Region, in FTEs



Source: EPA.

Note: Region 2 includes Puerto Rico and the U.S. Virgin Islands, Region 9 includes Hawaii, and Region 10 includes Alaska.

In addition, EPA's regional children's health coordinators told us their roles are neither set by the Office of Children's Health nor set to directly support agencywide, children-specific goals or strategies. Although the office facilitates information sharing among regional coordinators, primarily through monthly conference calls and an annual meeting, the 10 regional administrators determine the responsibilities, resources, and organizational placement of the children's environmental health coordinators within their respective region. For example, one EPA deputy regional administrator identified, as priority areas, three contaminants that pose risks to children—diesel, lead, and radon. The children's environmental health coordinator in that region subsequently sought resources from the program office to determine how to address these priorities and collaborate with ongoing projects in the region. In another region, priority setting was done from the "bottom up," driven largely by the availability of external (non-EPA) funding from sources such as nonprofit organizations. In addition, the Office of the Administrator has a lead coordinator who serves as a liaison between the regional offices and the eight suboffices within the Office of the Administrator (including the Office of Children's Health), but the lead also has a limited role determining EPA's children's health activities, with approximately one-eighth of their time working with the Office of Children's Health.

According to Office of Children's Health officials, most EPA regions do not have a dedicated budget to support the children's health coordinators. Often, coordinators must take the initiative to obtain assistance, or get logistical support, from other staff from the EPA branch or division in which they are located. As shown in table 3, the organizational placement of the children's coordinators also varies widely across the regions. That regional structure has led to differing priorities across regions, which may be appropriate in some circumstances when coordinators need to respond to unique regional children's health challenges, but does not provide a consistent organizational mechanism that integrates the Office of Children's Health or institutionalizes the Administrator's top children's health priorities across the regions.

Table 3: Placement of EPA's Regional Children's Health Coordinators within the Offices of the Regional Administrator

EPA region	Organizational placement
1	Office of Public Affairs
2	Office of Strategic Programs
3	Environmental Assessment and Innovation Division Office of Environmental Innovation
4	Air, Pesticides and Toxics Management Division Pesticides and Toxics Substances Branch Children's Health, Lead and Asbestos Section

EPA region	Organizational placement
5	Land and Chemicals Division Chemical Management Branch
6	Multimedia Planning and Permitting Division Toxics Branch
7	Office of Public Affairs
8	Office of Partnerships And Regulatory Assistance State Partnerships and Sustainable Practices Program
9	Office of Public Affairs
10	Office of Ecosystems, Tribal, and Public Affairs Ecosystems, Community Health, and Environmental Justice Branch

Source: GAO based on EPA information.

According to EPA officials, a key factor in ensuring effective regional children's health coordinators is strong leadership and direction from the EPA Administrator and other top EPA officials. While regional administrators and other managers were involved in agencywide strategy and priority setting exercises related to children's health issues starting in early 2001, such efforts have not taken place since 2003. At present, there is no formal, agencywide effort in which EPA's regional or deputy administrators involve themselves in children's health issues. Instead, EPA staff told us that many EPA regions react to children's health crises, rather than proactively supporting programs to prevent children's health problems before they arise. Furthermore, regional administrators may or may not take direction from the Office of Children's Health, and several EPA officials stated that the office has rarely communicated its priorities to the EPA regional administrators or deputy regional administrators.[58] The office recently told us that the new director has discussed his five-point approach in a call with the deputy regional administrators and visited four regional offices to discuss children's health with regional staff and managers.

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[58] EPA's Inspector General recommended in his 2004 report that coordination be reflected in EPA's strategic plan objectives and in relevant output and outcome performance indicators.

EPA Has Made Little Use of Its Children's Health Protection Advisory Committee

In September 2008, we testified that EPA had not proactively used its Children's Health Protection Advisory Committee to maintain a focus on protecting children's environmental health.[59] As we said earlier, the Advisory Committee was established to provide advice, consultation, and recommendations to EPA in the areas of research, community outreach, and the development of regulations, guidance, and policies. EPA rarely sought out the Advisory Committee's advice in those areas, despite convening the committee 33 times between 1998 and 2008 for presentations and discussions with EPA and non-EPA officials. We identified only four instances where EPA specifically asked for the committee's advice on research, three instances on outreach, four instances on regulations, and two instances on guidance. We did not identify any instances where EPA sought out the committee's advice on policies, including the Policy on Evaluating Health Risks to Children, which has not been updated since it was established in 1995.

Nonetheless, the members of the Advisory Committee drafted and approved 74 letters to the Administrator between 1998 and 2008, to which EPA responded 53 times (about 73 percent). Those letters contained a range of information, advice, and recommendations. The Advisory Committee's letters offered EPA hundreds of recommendations about a variety of topics related to reducing environmental health risks to children. We identified 607 recommendations during our review of the Advisory Committee's letters. A small number of letters contained recommendations relating to multiple children's environmental health issues, such as a May 2008 letter with recommendations about mercury regulation, farm worker protection standards, organophosphate pesticides, and air quality. However, most letters contained recommendations on a single issue. The number of recommendations varied from year to year, ranging from 120 in 2000 to 20 in 2001. We placed the 607 recommendations into 10 categories that demonstrate the breadth and depth of the Advisory Committee's concerns. Figure 4 shows the number of recommendations in each category. Some recommendations were placed into multiple categories when, for example, a recommendation was related to "research" and "policy and procedures."[60]

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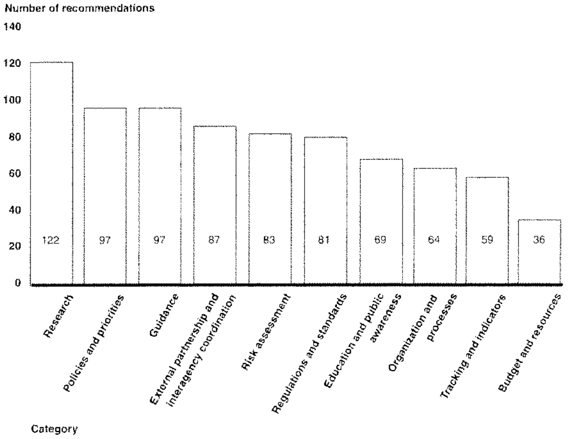
[59] GAO-08-1155T.

[60] For example, we placed the following June 2008 Advisory Committee recommendation into both the research and the policy and procedure categories: "Additional research on children's vulnerabilities to health impacts of climate change should also be a priority for the agency as a whole in the future."

The largest category of recommendations concerned how EPA conducts, prioritizes, and utilizes research on children's environmental health. The next largest categories involved the agency's policies and priorities and the development and use of guidance documents.

Figure 4: Number of Children's Health Protection Advisory Committee Recommendations by Category



Source: GAO analysis of Advisory Committee letters.

Note: Because recommendations may appear in multiple categories, the number of recommendations shown in the figure exceeds the total number of recommendations.

In our September 2008 testimony, we also stated that EPA had not substantially addressed key Advisory Committee recommendations. For example, EPA had not specifically acknowledged 11 of the Advisory Committee's 23 recommendations concerning proposed revisions to the NAAQS for particulate matter, ozone, and lead. EPA did provide the Advisory Committee with official response letters to six of its seven NAAQS-related letters, but generally did not acknowledge or was noncommittal to the Advisory Committee's recommendations. Instead, it provided a generic statement about considering the recommendations with all other public comments. We also testified that EPA had not fulfilled its commitment to address key recommendations submitted to EPA by the Advisory Committee on the 10th anniversary of the Executive Order. The Advisory Committee's April 10, 2007, letter provided recommendations in seven areas for renewing EPA's vision on children's environmental health and its commitment to the principles outlined in the order. EPA's June 13, 2007, response letter directed the Office of Children's Health to work collaboratively with program offices across the agency and committed the agency to working with the Advisory Committee to review these recommendations. However, while the office established workgroups within its Children's Health Advisory Management Partners group to address each of the seven areas outlined by the Advisory Committee, a new acting director stopped the process in late 2007.

In our September 2008 testimony, we recommended that the Administrator examine ways to more proactively use the Advisory Committee to reinvigorate the agency's focus on protecting children's health. Since that time, EPA's Administrator and the Director of EPA's Office of Children's Health have met with the Advisory Committee in March and July 2009, respectively. In his remarks to the Advisory Committee, the Director expressed his commitment to more proactively use the Advisory Committee to support EPA's efforts to protect children's health. Specifically, he said that EPA could more effectively use the Advisory Committee for advice in developing regulations, and he asked for input on how to engage the Advisory Committee early and often in rulemakings. He also said that the committee could provide leadership in the area of science policy at EPA. He told the committee that it could advise EPA on developing policies for conducting research and making decisions in instances where EPA lacks conclusive information about children's vulnerabilities. For example, the Director recently asked the committee to provide EPA with advice on its draft school siting guidelines.

Opportunities Exist for EPA to Lead and Coordinate National Efforts to Protect Children from Environmental Threats

The Executive Order provides EPA with opportunities for leadership and coordination across the federal government. Key provisions of the Executive Order, specifically an interagency task force that reports to the President on federal research priorities—were allowed to lapse in 2005. There are other federal opportunities to set national goals and indicators related to children's environmental health, such as the Interagency Forum on Child and Family Statistics and Healthy People 2020.

Task Force Provided High-level Opportunities for Strategy Development and Interagency Coordination until It Expired in 2005

The President's Task Force on Children's Environmental Health Risks and Safety Risks was authorized by the Executive Order in April 1997 for a period of 4 years to provide high-level leadership and interagency coordination on children's environmental health. It comprised nine cabinet officials and seven White House office directors and was co-chaired by the Administrator of EPA and the Secretary of the Department of Health and Human Services. The Task Force convened five times for meetings in October 1997, April 1998, January 1999, September 1999, and October 2001. As part of National Children's Health Month in October 2001, the President extended the Task Force for 2 years. According to EPA officials, the Administrator urged the President to continue the Task Force; in April 2003, the President extended it for a final 2 years. However, the final order eliminated the provision for reassessing the need for continuance of the Task Force, which was not convened after the October 2001 meeting. According to EPA officials involved on the steering committee, the agency was not able to convene the Task Force thereafter, for reasons related to new priorities following the September 11, 2001, terrorist attacks. Nonetheless, a senior career-level staff steering committee continued to meet until 2005 to coordinate and implement the strategies that the Task Force developed to address the threats to children's health.

The Task Force contributed to eight areas which related to children's health, including the establishment of the National Children's Study, the largest long-term study of environmental influences on children's health and development. The study was proposed and developed through the cooperation of four agencies, including EPA, to examine the effects of environmental influences on the health and development of more than 100,000 children across the nation, following them from before birth until age 21. It was initiated as part of the Children's Health Act of 2000.

The Task Force also identified four major environmental and safety threats to children—asthma, developmental disabilities (including lead poisoning), cancer, and unintentional injuries—and created national strategies for each of them. In its strategy documents, the Task Force recognized that an integrated solution was needed across the federal government to address the complex interaction between a child's biology, behavior, and the physical, chemical, biological, and social environment. According to the children's health experts with whom we spoke—including EPA's first senior advisor for children's health and the first director of the office—the Task Force provided critical leadership on several important initiatives such as the National Children's Study and the Healthy School Environments Assessment Tool (HealthySEAT). These national programs focus heavily on the environmental influences on children's health, with the National Children's Study examining the role of environmental factors on health and disease and Healthy SEAT offering school districts a self-assessment tool for identifying and evaluating environmental, safety, and health hazards.

In addition, the departments and agencies that made up the Task Force partnered to prepare a fiscal year 2001 interagency budget initiative to fund the Task Force's initiatives in the four priority areas. The Secretary of Health and Human Services and the Administrator of EPA submitted the request to OMB with the recommendation that it be included as part of the President's budget request that year. EPA officials told us that OMB's involvement helped ensure that adequate funds were available to these agencies to address children's health. This interagency budgeting effort did not contiuue past the last meeting of the Task Force in 2001.

Since the Task Force's expiration, EPA and the Department of Health and Human Services no longer have a high-level infrastructure or mandate to coordinate federal strategies for children's environmental health and safety. According to the EPA staff and children's health experts with whom we spoke, had the Task Force continued, it could have helped the federal government respond to the health and safety concerns that prompted the 2007 recall of 45 million toys and children's products. Furthermore, since the Task Force provision of the Executive Order expired in 2005, the Task Force's reports are no longer generated. Those reports collected and detailed the interagency research, data, and other information "necessary to enhance the country's ability to understand, analyze, and respond to environmental health risks to children."

The Task Force was also charged with preparing reports on research, data, and other information that would enhance the federal government's ability to understand, analyze, and respond to environmental health risks to children. In the 2003 order to extend the Task Force, the President also directed that each report detail the accomplishments of the Task Force from the date of the preceding report. Through the biennial reporting process, each agency on the Task Force identified and described key data needs related to environmental health risks to children that had arisen in the course of the agency's programs and activities. The reports were made available to the public and intended for use by the Office of Science and Technology Policy and the National Science and Technology Council to establish national research priorities.

EPA Has Had Varied Involvement in Federal Interagency Forum on Child and Family and Children Statistics

The Executive Order also formally established the Interagency Forum on Child and Family Statistics, made up of representatives from federal statistics and research agencies and convened by the Director of OMB.[61] The order required the forum to publish an annual report on the most important indicators of the well-being of the country's children. As a result, the forum has published America's Children: Key National Indicators of Well-Being each year since 1997. The 2003 amendments to the Executive Order required the forum to begin publishing the report biennially. Accordingly, the forum issued a brief report in 2004 to highlight selected indicators, and it publishes the full report on alternate years. The Interagency Forum also updates all indicators and background data each year on its Web site.[62]

According to the forum's 2009 report:

> One important measure of children's environmental health is the percentage of children living in areas in which air pollution levels are higher than the allowable levels of the Primary National Ambient Air Quality Standards. These standards, established by the U.S. Environmental Protection Agency under the Clean Air Act, are designed to protect public health, including the health of susceptible populations such as children and individuals with asthma. Ozone, particulate matter, sulfur dioxide, and nitrogen dioxide are air pollutants associated with increased asthma episodes and other respiratory illnesses. Lead can affect the development of the central nervous system in young children, and exposure to carbon monoxide can reduce the capacity of blood to carry oxygen.

Table 4 shows the key national indicators for physical environment and safety from the 2009 report.

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[61] The forum was founded in 1994 to foster the coordination and integration of the collection and reporting of data on children and families.

[62] http://childstats.gov.

Table 4: Key Physical Environment and Safety Indicators of Children's Well-Being, 2009

Indicator	Measure	Previous value (year)	Most recent value (year)	Change between years
Outdoor and indoor air quality	Children ages 0-17 living in counties in which levels of one or more air pollutants were above allowable levels	66% (2006)	66% (2007)	NS
Drinking water quality	Children served by community water systems that did not meet all applicable health-based drinking water standards	9% (2006)	8% (2007)	NS
Lead in the blood of children	Children ages 1-5 with blood lead level greater than or equal to 10 µg/dL	2% (1999-2002)	* (2003-2006)	NS
Housing problems	Households with children ages 0-17 reporting shelter cost burden, crowding, and/or physically inadequate housing	40% (2005)	43% (2007)	NS
Youth victims of serious violent crimes	Serious violent crime victimization of youth ages 12-17	14 per 1,000 (2005)	10 per 1,000 (2006)	NS
Child injury and mortality	Injury deaths of children, ages 1-4	13 per 100,000 (2005)	12 per 100,000 (2006)	NS
	Injury deaths of children, ages 5-14	8 per 100,000 (2005)	7 per 100,000 (2006)	↓
	Injury deaths of adolescents, ages 15-19	50 per 100,000 (2005)	50 per 100,000 (2006)	NS

Source: Forum on Child and Family Statistics, America's Children: Key National Indicators of Well-Being, 2009.

Notes:

* = Percentage is not shown because sample is too small to provide a statistically reliable estimate.

NS = No statistically significant change.

↑ = Statistically significant increase.

↓ = Statistically significant decrease.

The forum's reports provide substantial detail about each indicator, including its relationship to children's health, and identify important areas where indicators are needed. For example, the 2009 report identified the need for a broader set of indicators on (1) body burden measurements (i.e., levels of contaminants in blood and urine) to characterize children's exposures, and (2) environmental quality to assess indoor air contaminants other than environmental tobacco smoke (e.g., pesticides) in homes, schools, and day care settings and for cumulative exposures to multiple environmental contaminants that children encounter daily.

Our analysis of EPA's involvement in the forum showed that the agency has not been consistently involved over the years. EPA had nearly no involvement in the first three reports—1997, 1998, and 1999—and, not surprisingly, those reports contained no indicators related to children's environmental health. Beginning with the 2000 report, the Director of the

Office of Children's Health helped lead the establishment of an indicator on air pollution (i.e., the NAAQS). That report identified the need for indicators to describe children's potential exposure to contaminants in drinking water and food. Subsequent reports began including an expanded set of indicators, including one for drinking water. Beginning in 2003, EPA's newly created Office of Environmental Information led EPA's involvement. In 2008, EPA's Office of Children's Health was again made the lead office for the agency. The official contact for the office is its Director of the Child and Aging Health Protection Division, who recently told us that the office again is participating and coordinating with other offices such as the EPA's Office of Policy, Economics, and Innovation.

Additional Federal Efforts to Address Children's Environmental Health Risks

In addition to the provisions of the Executive Order, there are other federal opportunities to address children's environmental health, including Healthy People 2010 and Healthy People 2020 and the international commitments to environmental health through the G8 (Group of Eight) countries. Healthy People is led by the Department of Health and Human Services and is composed of 28 focus areas with a total of 467 objectives and targets, including 17 on environmental quality. Within each area, Healthy People selected a few leading indicators. The Healthy People 2010 leading indicators for environmental quality are:

- reduce the proportion of children, adolescents, and adults that are exposed to ozone above the EPA standard from 43 percent (in 1997) to 0 percent (by the year 2010), and
- reduce the proportion of nonsmokers exposed to environmental tobacco smoke (i.e., secondhand smoke) from 65 percent (in 1988-1994) to 45 percent (in 2010).

According to Healthy People 2010, these indicators were selected because poor air quality contributes to respiratory illness, cardiovascular disease, and cancer. For example, asthma can be triggered or worsened by exposure to ozone, and while the overall death rate from asthma increased 57 percent from 1980 to 1993, for children it increased 67 percent. Healthy People 2010 is national in scope and includes identifying health indicators, collecting data, and reporting on progress toward meeting a range of health goals. In fact, the data sources for tracking most environmental indicators come from EPA.

EPA's environmental regulations and standards are key to achieving national environmental health objectives. EPA was not a lead federal agency in efforts to develop the Healthy People 2010 goals and indicators for environmental quality or the Federal Interagency Workgroup for Healthy People 2020. The agencies involved in Healthy People 2010 and 2020 are the Agency for Toxic Substances and Disease Registry, CDC, and the National Institutes of Health—each within the Department of Health and Human Services, the department that formerly co-chaired the Task Force with EPA.

With regard to international agreements, while the United States reiterated its commitment to protect children from environmental threats at the most recent meeting of the G8 environmental ministers, EPA has not undertaken an evaluation of its progress since 2002 or considered opportunities for a broader leadership role. The environmental ministers of the G8 countries declared that children's environmental health was a shared priority among the eight countries at their meeting in Miami, Florida, in May 1997.[63] They developed *the Declaration of the Environmental Leaders of the Eight on Children's Environmental Health* (Miami Declaration) that provided a framework for domestic, bilateral, and international actions by member nations to improve protection of children's health from seven environmental threats. In 2002, the Government of Canada published a status report on the implementation of the Miami Declaration. Table 5 lists the seven issues and key commitments, along with a brief progress summary from Canada's report. Notably, the status update for U.S. commitments on lead and air quality refer to two of the national strategies developed by the now-defunct President's Task Force.

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[63] The G8 countries are Canada, France, Germany, Italy, Japan, Russia, the United Kingdom, the United States, as well as the European Commission. The most recent meeting of the G8 took place in Italy in April 2009.

Table 5: Summary of Commitments and U.S. Implementation of the 1997 Miami Declaration, as of 2002

Children's environmental health issue	Key commitment	Status update
Risk assessment and standard setting	"We pledge to establish national policies that take into account the specific exposure pathways and dose-response characteristics of children when conducting environmental risk assessments and setting protective standards."	Implementation of the Food Quality Protection Act requires an additional 10-fold margin of safety for threshold effects
Lead	"We call for further actions that will result in reducing blood lead levels in children to below 10 micrograms per deciliter. Where this blood lead level is exceeded, further action is required."	Implementation of the federal Strategy to Eliminate Childhood Lead Poisoning by 2010
Microbiologically safe drinking water	"We agree to focus increased attention on drinking water disinfection, source water protection and sanitation...."	There are new final rules for Cryptosporidium and disinfection by-products
Air quality	"We undertake to reduce air pollution in our respective countries. We agree to exchange information on indoor air health threats and remedial measures."	Implementation of Asthma and the Environment: An Action Plan to Protect Children
Environmental tobacco smoke (ETS)	"We agree to cooperate on education and public awareness efforts aimed at reducing children's exposure to environmental tobacco smoke."	A new national public information campaign focuses on reducing at-risk children's exposure to ETS and other indoor and outdoor asthma triggers
Endocrine disrupting chemicals (EDC)	"We encourage continuing efforts to compile an international inventory of research activities, develop an international science assessment...identify and prioritize research needs and data gaps, and develop a mechanism for coordinating and cooperating on filling research needs. We pledge to develop cooperatively risk management or pollution prevention strategies, as major sources and environmental fates of endocrine disrupting chemicals are identified and will continue to inform the public as new knowledge is gained."	The United States has a research program on EDCs and a screening program
Climate change	The declaration does not contain any specific commitments on this issue but recognized that "action must be taken to confront the problem of global warming" given that "children and future generations face serious threats to their health and welfare from changes in the Earth's climate."	Global Change Research Program includes human health assessments

Source: Excerpts from Government of Canada, *Status Report on the Implementation of the 1997 Declaration of the Environment Leaders of the Eight on Children's Environmental Health* (2002).

EPA has not undertaken an evaluation of its progress toward the country's international commitments for children's environmental health. Nor has the United States taken a leadership role in updating or reissuing specific new commitments since the 1997 declaration. At the April 2009 meeting of the G8, the EPA Administrator cited the declaration, highlighted subsequent U.S. activities, and provided examples of other countries' actions—including Europe's new chemicals policy and the World Health Organization's Children's Environment and Health Action Plan.[64] The Administrator closed her remarks to the environmental ministers by stating,

> We have learned much in the last 12 years about the ways that environmental exposures uniquely affect children. With that increased knowledge, our sense of urgency for further action on children has also increased….The U.S. government, under this new administration, will keep faith with the promise we've made to future generations. I hope we can continue the work we started in 1997, renewing our commitment to protect children from environmental threats where they live, learn, work and play.

Conclusions

Since the President signed Executive Order 13045 in 1997, every EPA Administrator has stated that children's environmental health is a priority at the agency. However, the momentum seen in the goals, strategies, and accomplishments for children's health that resulted from that initiative more than a decade ago has not been sustained through succeeding EPA administrators. Instead, we have seen diminished leadership, planning, and coordination at EPA and across the federal government with regard to children's environmental health. In the intervening years, research has only further substantiated the importance that environmental exposures have during development—from before birth, through early childhood and adolescence, and into adulthood. The possibility that exposure to environmental contaminants may have lifelong health consequeuces for an individual person—and subsequent generations—is a paradigm shift in sophistication from the idea that "children are not just little adults," an idea that was groundbreaking in the early 1990s. In order to continue making progress toward protecting children from environmental health threats, we believe EPA needs to reinvigorate its leadership and focus on children's environmental health in concrete and actionable ways.

Notwithstanding the actions that EPA can take on its own, leadership from outside the agency will likely be needed for sustained progress toward protecting children from current and emerging environmental threats. As we stated in our testimony, the Children's Health Protection Advisory Committee and the President's Task Force on Children's Environmental

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[64] Administrator Lisa P. Jackson, Remarks at the G8 Environmental Minister's Meeting Children's Health Event, April 24, 2009.

Health Risks and Safety Risks have served as two such entities. The Advisory Committee has provided strategic, specific, and often unsolicited advice to EPA over the past decade. We continue to believe that EPA could do more to fully utilize that body of experts to inform EPA's developing regulations and generally support the agency's efforts to protect children's health.[65] Engaging the committee early and often in rulemakings and providing leadership in the area of science policy and other areas where EPA may lack conclusive information about children's vulnerabilities would take advantage of the Advisory Committee's expertise and reinvigorate its original purpose. The President's Task Force that expired in 2005 provided high-level infrastructure to coordinate federal strategies for children's environmental health and safety problems such as asthma, as well as data needs. Furthermore, the Task Force documented its accomplishments to the President in reports that detailed its members' efforts to enhance the nation's ability to understand, analyze, and respond to environmental health risks to children. EPA staff and children's health experts told us the Task Force could help the federal government respond to national health and safety concerns, such as recalls of toys and other children's products. Because the Task Force included nine cabinet officials and seven White House office directors and was co-chaired by the Administrator of EPA and the Secretary of Health and Human Services, it provided the leadership and authority needed to address children's environmental health issues of national scope. We see opportunity for EPA to take a leadership role and identify, assess, and address the environmental health challenges of the 21st century such as low levels of toxic chemicals that may cause cancer and induce reproductive or developmental changes in the nation's children.

Recommendations for Executive Action

To help ensure that EPA assumes high-level leadership and develops strategies and structures for coordinating efforts addressing children's environmental health both within the agency and throughout the federal government, we are making eight recommendations for executive action.

To maximize opportunities to institutionalize children's health throughout the agency, we recommend that the EPA Administrator take the following actions:

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[65] GAO-08-1155T.

- update and reissue a child-focused strategy, such as the 1996 National Agenda, to articulate current national environmental health priorities and emerging issues;
- strengthen the data system that identifies and tracks development of rulemakings and other actions to ensure they comply with the 1995 policy on evaluating health risks to children;
- re-evaluate the 1995 policy to ensure its consistency with new scientific research demonstrating the risks childhood exposures can have on risks for disease in later lifestages;
- ensure that the EPA's 2009-2013 strategic plan expressly articulates children-specific goals, objectives and targets;
- re-evaluate the mission of the Office of Children's Health Protection and its director to make the office an agencywide champion for implementation of a reissued national children's environmental health agenda, policy, and related goals in the next EPA strategic plan;
- establish key children's environmental health staff within each program office and regional office, with linkages to the Office of Children's Health, to improve cross-agency implementation of revised priorities and goals, and ensure coordination and communication among EPA's program offices;
- use the Children's Health Protection Advisory Committee proactively as a mechanism for providing advice on regulations, programs, plans, or other issues; and
- ensure participation, to the fullest extent possible, by the Office of Children's Health or other key officials on the interagency organizations identified in Executive Order 13045.

Matter for Congressional Consideration

Because EPA alone cannot address the complexities of the nation's challenges in addressing environmental health risks for children, we encourage Congress to re-establish a government-wide task force on children's environmental health risks, similar to the one previously established by Executive Order 13045 and co-chaired by the Administrator of EPA and the Secretary of Health and Human Services. We encourage Congress to charge it with identifying the principal environmental health threats to children and developing national strategies for addressing them. We further encourage Congress to establish in law the Executive Order's requirement for periodic reports about federal research findings and research needs regarding children's environmental health.

Agency Comments and Our Evaluation

We provided EPA with a draft of this report for review and comment. EPA stated that the report accurately portrays the agency's challenges in addressing children's environmental health, and sets forth sound recommendations on steps that could be taken to better incorporate protection of children's health as an integral part of EPA's everyday business. EPA also commented that implementing the recommendations provided in this report will bring the agency a long way to achieving its goals for protecting children's health. EPA's written comments are in appendix V. In addition, EPA provided technical comments, which we incorporated into the report as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from its issuance. At that time, we will send copies of this report to interested congressional committees, the Administrator of the Environmental Protection Agency, and other interested parties. The report also will be available at no charge on GAO's Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-3841 or stephensonj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix VI.

John B. Stephenson
Director, Natural Resources
and Environment

Appendix I: Scope and Methodology

Our report objectives were to examine (1) the extent to which the Environmental Protection Agency's (EPA) policies, plans, and guidance have served to institutionalize the agency's consideration of children's environmental health; (2) the extent to which EPA has utilized its children's health office and other child-focused resources; and (3) what opportunities exist for EPA to provide national leadership in addressing current and emerging environmental risks to children's health.

To address our first objective, we obtained and analyzed key EPA children's health-related policies, strategic and performance plans, guidance documents, and selected children's indicator reports, and referred to long-established quality management criteria from the Government Performance Results Act. We considered EPA's "2006-2011 Strategic Plan: Charting Our Course," "2003-2008 Strategic Plan: Direction for the Future," "EPA Strategic Plan: 2000-2005," "EPA Strategic Plan: 1997-2003," as well as EPA's forthcoming strategic plan, "2009-2013 Strategic Plan: Change Document," which was in draft form at the time of our review. We analyzed the goals, objectives, and strategic targets of these documents in order to determine the extent that they address children's health. We reviewed EPA's performance and accountability reports to identify performance measures associated with identified children's health objectives and strategic targets. We discussed the plans and reports with officials from EPA's Office of the Chief Financial Officer, including staff from the Office of Planning, Analysis, and Accountability. We also reviewed OMB Circular No. A-11 on guidance to agencies preparing materials required for strategic plans and annual program performance reports. We reviewed EPA *Federal Register* notices for regulations subject to the regulatory requirements of the order as well as documents detailing EPA's rulemaking for its National Ambient Air Quality Standards for Particulate Matter published in October 2006. We also reviewed children's health data that EPA maintains in its regulatory tracking database.

To address our second objective, we used NVivo, a content analysis software package, to analyze 35 Advisory Committee meeting agendas and related summaries derived from meetings held bi- or tri-annually between December 1997 and July 2009. Content analysis is a methodology for structuring and analyzing written material. We also used the software to analyze 74 Children's Health Protection Advisory Committee (Advisory Committee) letters sent to EPA and 53 EPA response letters, issued between May 1998 and December 2008. Our internal team of subject matter and methodological experts developed a coding scheme for identifying (1) recommendations, which we defined as any and all statements made in Advisory Committee letters that advise, ask, request, suggest, or urge EPA to take action; and (2) EPA requests of the Advisory Committee, which we defined as formal or incidental requests for advice or input by EPA to its Advisory Committee. Recommendations were identified in Advisory Committee letters sent to EPA. In some cases, a single sentence contained multiple recommendations. For example, the Advisory Committee wrote "EPA should show leadership in applying stringent mercury controls in our own coal-fired power plants and involve the U.S. in technology transfer to improve emissions in other parts of the world," which we coded as two recommendations. EPA requests of the Advisory Committee were identified in meeting summaries, which represent the official and complete record of proceedings. Other requests—for example, individually from an EPA official to an individual Advisory Committee member—were not considered requests as the entire Advisory Committee must be informed and consensus must be reached by the Advisory Committee on all matters, as specified in its charter.

To characterize the range of issues recommended to EPA by its Advisory Committee, we developed content analysis categories based on a review of the Advisory Committee's charter and an initial review of the letters. We then coded each recommendation into one or more of the following 10 categories:

- budget and resources (financing, funding, or the need to change resource levels for a program or issue),
- education and public awareness (providing information to the public through different media outlets),
- organization and processes (how EPA is organized, including how it operates, the form or function of EPA management, and its internal processes and procedures),
- policies and priorities (advising EPA to amend, go forward with, or cease a particular policy or prioritization that directly or indirectly may impact children's health),
- external partnership and inter-agency coordination (how EPA coordinates or collaborates with other agencies or entities),
- guidance (developing, updating and using guidance documents and related information resources),

- regulations and standards (EPA regulations and its work setting or influencing EPA or government-wide standards),
- research (conducting, funding, utilizing, or prioritizing research that would benefit children's health),
- risk assessment (development of risk assessment protocols, and selecting assumptions, risk factors, and margins of error), and
- tracking and indicators (tracking environmental pollutants, as well as monitoring such pollutants and/or observing human health outcomes over time).

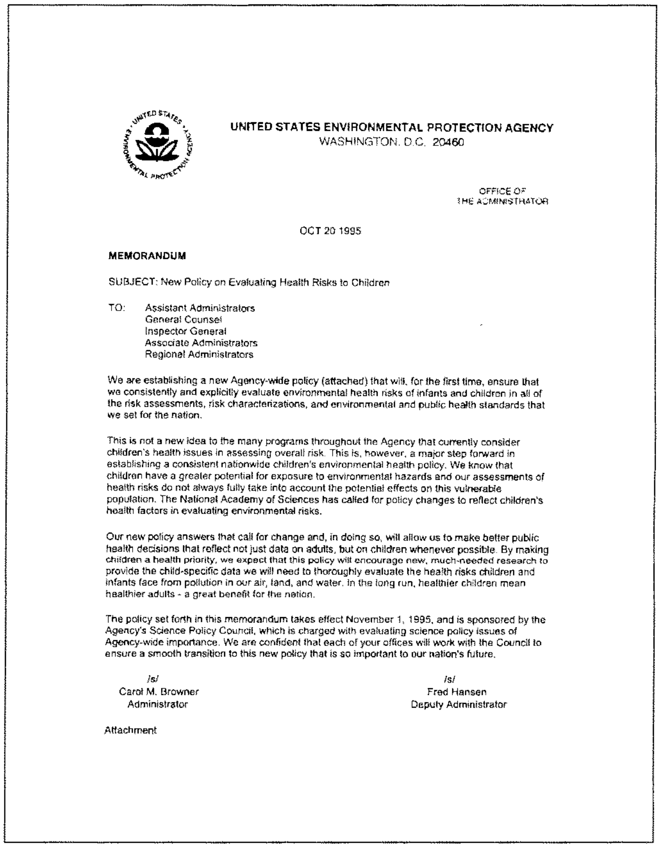
The content analysis was conducted by two analysts, and discrepancies in coding were discussed and agreement reached between the analysts, or resolved through a third analyst review. Our analysis produced an inventory of Advisory Committee recommendations and EPA requests of the Advisory Committee.

We also interviewed officials from EPA program offices most directly involved with children's health issues: the Office of Children's Health Protection, including current and former office directors; the Office of Research and Development; the Office of Pesticide Programs; and the Office of Policy, Economics and Innovation. We interviewed EPA's regional children's environmental health coordinators and lead regional coordinator within the Office of the Administrator. To gain further perspective on EPA's use of its children's health-focused resources, we interviewed leading children's health research and policy experts at nonprofit organizations and academic institutions, including those associated with EPA's Advisory Committee.

To address our third objective, we reviewed the annual reports from the Federal Interagency Forum on Child and Family Statistics to determine the extent of EPA's involvement in their development. We also interviewed staff involved with the children's task force and reviewed documents from the Task Force on Environmental Health Risks and Safety Risks to Children, including the strategy documents that were developed. We also reviewed documents related to the G8 Miami Declaration on Children's Environmental Health, including the 2002 *Status Report on Implementation of the 1997 Declaration of the Environmental Leaders of the Eight on Children's Environmental Health.*

We conducted this performance audit from November 2008 through January 2010 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: EPA Policy on Evaluating Health Risks to Children



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
THE ADMINISTRATOR

OCT 20 1995

MEMORANDUM

SUBJECT: New Policy on Evaluating Health Risks to Children

TO: Assistant Administrators
General Counsel
Inspector General
Associate Administrators
Regional Administrators

We are establishing a new Agency-wide policy (attached) that will, for the first time, ensure that we consistently and explicitly evaluate environmental health risks of infants and children in all of the risk assessments, risk characterizations, and environmental and public health standards that we set for the nation.

This is not a new idea to the many programs throughout the Agency that currently consider children's health issues in assessing overall risk. This is, however, a major step forward in establishing a consistent nationwide children's environmental health policy. We know that children have a greater potential for exposure to environmental hazards and our assessments of health risks do not always fully take into account the potential effects on this vulnerable population. The National Academy of Sciences has called for policy changes to reflect children's health factors in evaluating environmental risks.

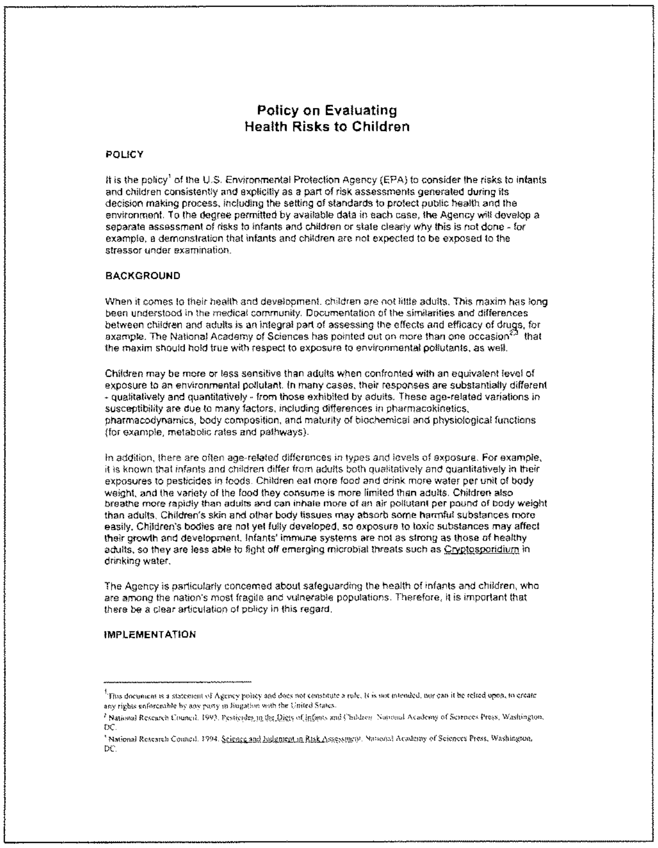
Our new policy answers that call for change and, in doing so, will allow us to make better public health decisions that reflect not just data on adults, but on children whenever possible. By making children a health priority, we expect that this policy will encourage new, much-needed research to provide the child-specific data we will need to thoroughly evaluate the health risks children and infants face from pollution in our air, land, and water. In the long run, healthier children mean healthier adults - a great benefit for the nation.

The policy set forth in this memorandum takes effect November 1, 1995, and is sponsored by the Agency's Science Policy Council, which is charged with evaluating science policy issues of Agency-wide importance. We are confident that each of your offices will work with the Council to ensure a smooth transition to this new policy that is so important to our nation's future.

/s/
Carol M. Browner
Administrator

/s/
Fred Hansen
Deputy Administrator

Attachment



Policy on Evaluating Health Risks to Children

POLICY

It is the policy[1] of the U.S. Environmental Protection Agency (EPA) to consider the risks to infants and children consistently and explicitly as a part of risk assessments generated during its decision making process, including the setting of standards to protect public health and the environment. To the degree permitted by available data in each case, the Agency will develop a separate assessment of risks to infants and children or state clearly why this is not done - for example, a demonstration that infants and children are not expected to be exposed to the stressor under examination.

BACKGROUND

When it comes to their health and development, children are not little adults. This maxim has long been understood in the medical community. Documentation of the similarities and differences between children and adults is an integral part of assessing the effects and efficacy of drugs, for example. The National Academy of Sciences has pointed out on more than one occasion[2,3] that the maxim should hold true with respect to exposure to environmental pollutants, as well.

Children may be more or less sensitive than adults when confronted with an equivalent level of exposure to an environmental pollutant. In many cases, their responses are substantially different - qualitatively and quantitatively - from those exhibited by adults. These age-related variations in susceptibility are due to many factors, including differences in pharmacokinetics, pharmacodynamics, body composition, and maturity of biochemical and physiological functions (for example, metabolic rates and pathways).

In addition, there are often age-related differences in types and levels of exposure. For example, it is known that infants and children differ from adults both qualitatively and quantitatively in their exposures to pesticides in foods. Children eat more food and drink more water per unit of body weight, and the variety of the food they consume is more limited than adults. Children also breathe more rapidly than adults and can inhale more of an air pollutant per pound of body weight than adults. Children's skin and other body tissues may absorb some harmful substances more easily. Children's bodies are not yet fully developed, so exposure to toxic substances may affect their growth and development. Infants' immune systems are not as strong as those of healthy adults, so they are less able to fight off emerging microbial threats such as Cryptosporidium in drinking water.

The Agency is particularly concerned about safeguarding the health of infants and children, who are among the nation's most fragile and vulnerable populations. Therefore, it is important that there be a clear articulation of policy in this regard.

IMPLEMENTATION

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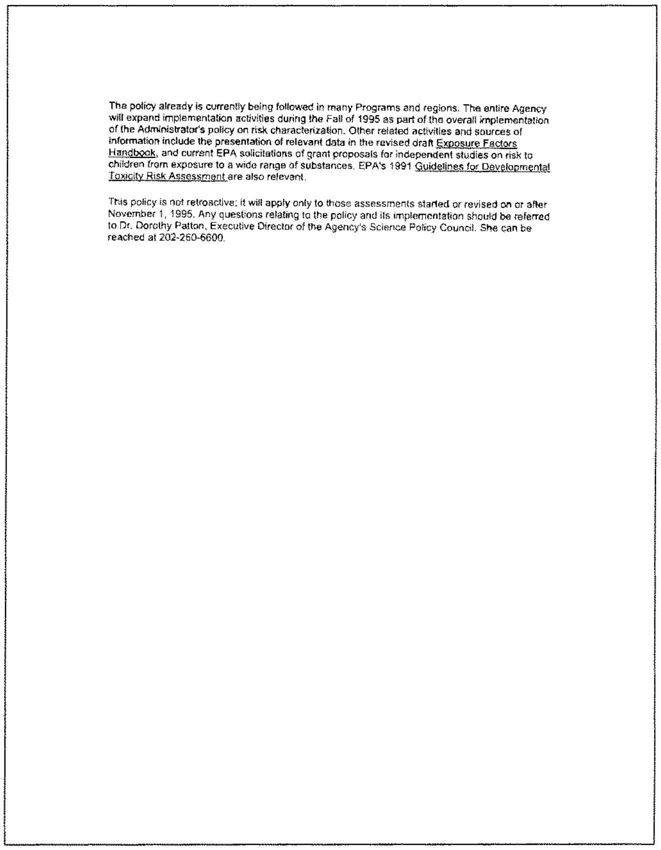
[1] This document is a statement of Agency policy and does not constitute a rule. It is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States.

[2] National Research Council. 1993. Pesticides in the Diets of Infants and Children. National Academy of Sciences Press, Washington, DC.

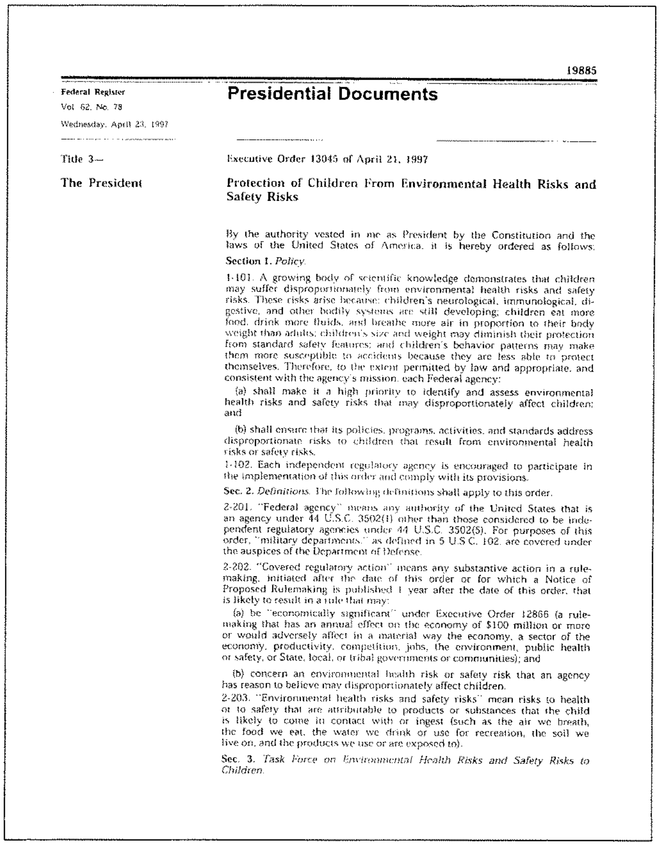
[3] National Research Council. 1994. Science and Judgment in Risk Assessment. National Academy of Sciences Press, Washington, DC.



The policy already is currently being followed in many Programs and regions. The entire Agency will expand implementation activities during the Fall of 1995 as part of the overall implementation of the Administrator's policy on risk characterization. Other related activities and sources of information include the presentation of relevant data in the revised draft Exposure Factors Handbook, and current EPA solicitations of grant proposals for independent studies on risk to children from exposure to a wide range of substances. EPA's 1991 Guidelines for Developmental Toxicity Risk Assessment are also relevant.

This policy is not retroactive; it will apply only to those assessments started or revised on or after November 1, 1995. Any questions relating to the policy and its implementation should be referred to Dr. Dorothy Patton, Executive Director of the Agency's Science Policy Council. She can be reached at 202-260-6600.

Appendix III: Executive Order 13045 and Amendments



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Federal Register
Vol. 62, No. 78
Wednesday, April 23, 1997

Presidential Documents

Title 3—

The President

Executive Order 13045 of April 21, 1997

Protection of Children From Environmental Health Risks and Safety Risks

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Policy.*

1-101. A growing body of scientific knowledge demonstrates that children may suffer disproportionately from environmental health risks and safety risks. These risks arise because: children's neurological, immunological, digestive, and other bodily systems are still developing; children eat more food, drink more fluids, and breathe more air in proportion to their body weight than adults; children's size and weight may diminish their protection from standard safety features; and children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves. Therefore, to the extent permitted by law and appropriate, and consistent with the agency's mission, each Federal agency:

(a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and

(b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks.

1-102. Each independent regulatory agency is encouraged to participate in the implementation of this order and comply with its provisions.

Sec. 2. *Definitions.* The following definitions shall apply to this order.

2-201. "Federal agency" means any authority of the United States that is an agency under 44 U.S.C. 3502(1) other than those considered to be independent regulatory agencies under 44 U.S.C. 3502(5). For purposes of this order, "military departments," as defined in 5 U.S.C. 102, are covered under the auspices of the Department of Defense.

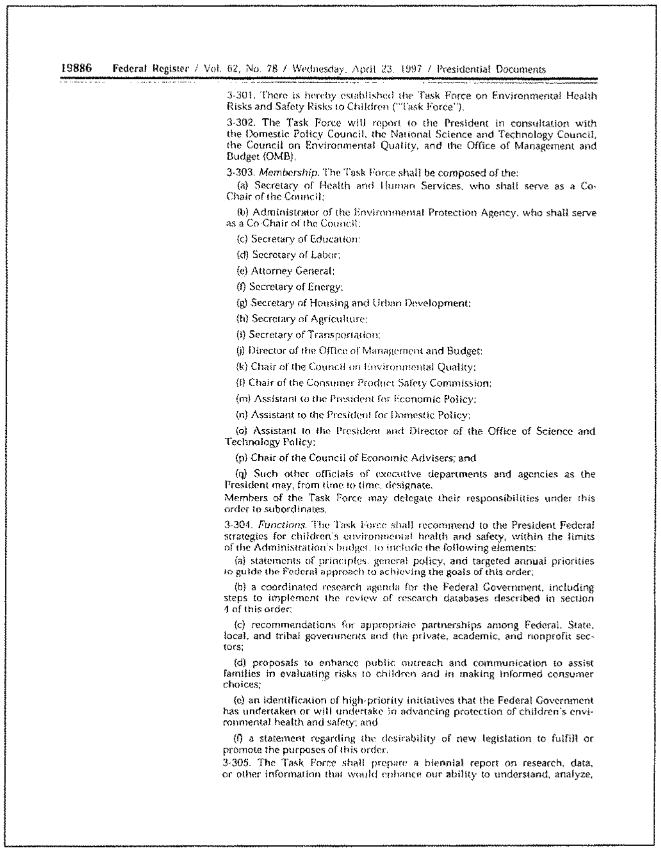
2-202. "Covered regulatory action" means any substantive action in a rulemaking, initiated after the date of this order or for which a Notice of Proposed Rulemaking is published 1 year after the date of this order, that is likely to result in a rule that may:

(a) be "economically significant" under Executive Order 12866 (a rulemaking that has an annual effect on the economy of $100 million or more or would adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities); and

(b) concern an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children.

2-203. "Environmental health risks and safety risks" mean risks to health or to safety that are attributable to products or substances that the child is likely to come in contact with or ingest (such as the air we breath, the food we eat, the water we drink or use for recreation, the soil we live on, and the products we use or are exposed to).

Sec. 3. *Task Force on Environmental Health Risks and Safety Risks to Children.*



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3-301. There is hereby established the Task Force on Environmental Health Risks and Safety Risks to Children ("Task Force").

3-302. The Task Force will report to the President in consultation with the Domestic Policy Council, the National Science and Technology Council, the Council on Environmental Quality, and the Office of Management and Budget (OMB).

3-303. *Membership.* The Task Force shall be composed of the:

(a) Secretary of Health and Human Services, who shall serve as a Co-Chair of the Council;

(b) Administrator of the Environmental Protection Agency, who shall serve as a Co-Chair of the Council;

(c) Secretary of Education;

(d) Secretary of Labor;

(e) Attorney General;

(f) Secretary of Energy;

(g) Secretary of Housing and Urban Development;

(h) Secretary of Agriculture;

(i) Secretary of Transportation;

(j) Director of the Office of Management and Budget;

(k) Chair of the Council on Environmental Quality;

(l) Chair of the Consumer Product Safety Commission;

(m) Assistant to the President for Economic Policy;

(n) Assistant to the President for Domestic Policy;

(o) Assistant to the President and Director of the Office of Science and Technology Policy;

(p) Chair of the Council of Economic Advisers; and

(q) Such other officials of executive departments and agencies as the President may, from time to time, designate.

Members of the Task Force may delegate their responsibilities under this order to subordinates.

3-304. *Functions.* The Task Force shall recommend to the President Federal strategies for children's environmental health and safety, within the limits of the Administration's budget, to include the following elements:

(a) statements of principles, general policy, and targeted annual priorities to guide the Federal approach to achieving the goals of this order;

(b) a coordinated research agenda for the Federal Government, including steps to implement the review of research databases described in section 4 of this order;

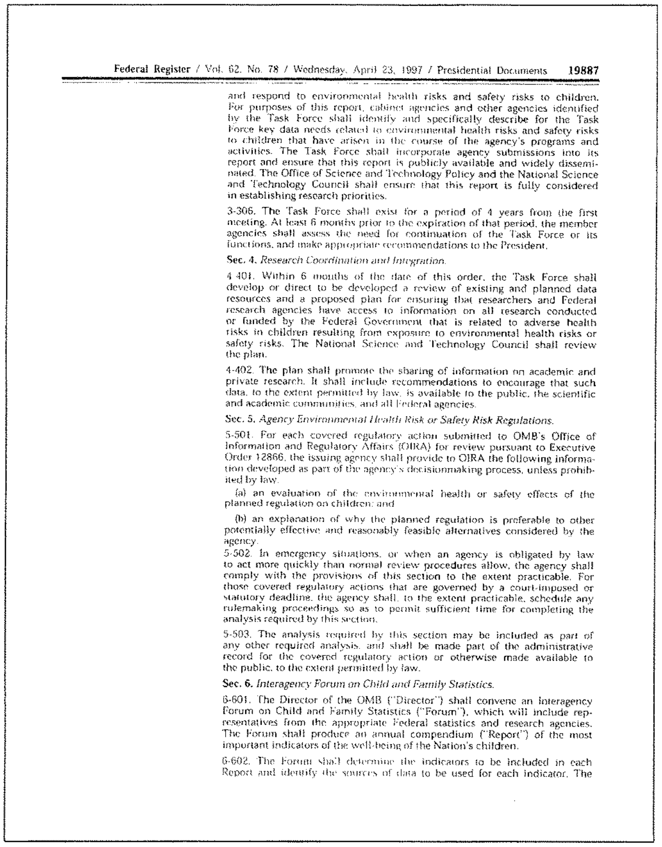
(c) recommendations for appropriate partnerships among Federal, State, local, and tribal governments and the private, academic, and nonprofit sectors;

(d) proposals to enhance public outreach and communication to assist families in evaluating risks to children and in making informed consumer choices;

(e) an identification of high-priority initiatives that the Federal Government has undertaken or will undertake in advancing protection of children's environmental health and safety; and

(f) a statement regarding the desirability of new legislation to fulfill or promote the purposes of this order.

3-305. The Task Force shall prepare a biennial report on research, data, or other information that would enhance our ability to understand, analyze,



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and respond to environmental health risks and safety risks to children. For purposes of this report, cabinet agencies and other agencies identified by the Task Force shall identify and specifically describe for the Task Force key data needs related to environmental health risks and safety risks to children that have arisen in the course of the agency's programs and activities. The Task Force shall incorporate agency submissions into its report and ensure that this report is publicly available and widely disseminated. The Office of Science and Technology Policy and the National Science and Technology Council shall ensure that this report is fully considered in establishing research priorities.

3-306. The Task Force shall exist for a period of 4 years from the first meeting. At least 6 months prior to the expiration of that period, the member agencies shall assess the need for continuation of the Task Force or its functions, and make appropriate recommendations to the President.

Sec. 4. *Research Coordination and Integration.*

4-401. Within 6 months of the date of this order, the Task Force shall develop or direct to be developed a review of existing and planned data resources and a proposed plan for ensuring that researchers and Federal research agencies have access to information on all research conducted or funded by the Federal Government that is related to adverse health risks in children resulting from exposure to environmental health risks or safety risks. The National Science and Technology Council shall review the plan.

4-402. The plan shall promote the sharing of information on academic and private research. It shall include recommendations to encourage that such data, to the extent permitted by law, is available to the public, the scientific and academic communities, and all Federal agencies.

Sec. 5. *Agency Environmental Health Risk or Safety Risk Regulations.*

5-501. For each covered regulatory action submitted to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to Executive Order 12866, the issuing agency shall provide to OIRA the following information developed as part of the agency's decisionmaking process, unless prohibited by law:

(a) an evaluation of the environmental health or safety effects of the planned regulation on children; and

(b) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.

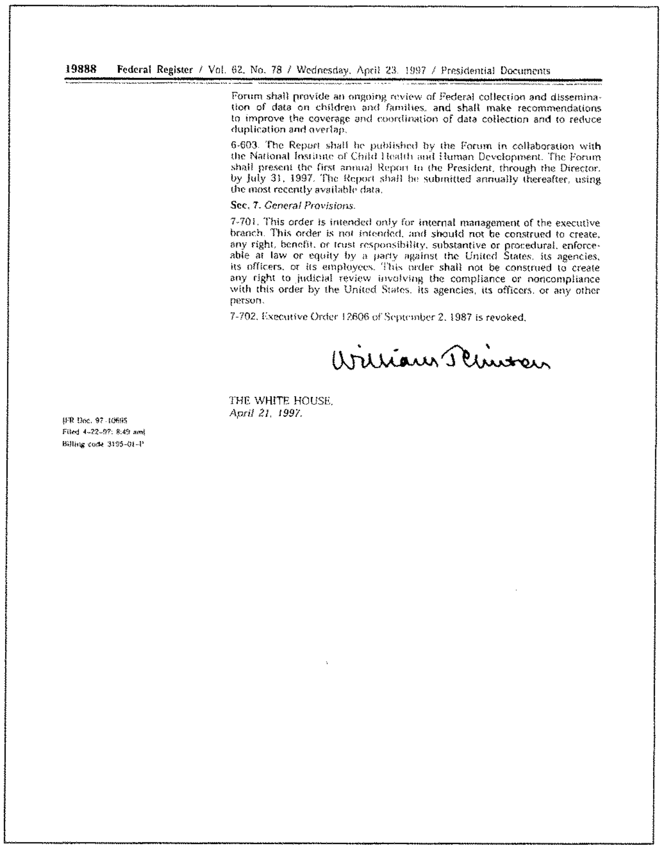
5-502. In emergency situations, or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall comply with the provisions of this section to the extent practicable. For those covered regulatory actions that are governed by a court-imposed or statutory deadline, the agency shall, to the extent practicable, schedule any rulemaking proceedings so as to permit sufficient time for completing the analysis required by this section.

5-503. The analysis required by this section may be included as part of any other required analysis, and shall be made part of the administrative record for the covered regulatory action or otherwise made available to the public, to the extent permitted by law.

Sec. 6. *Interagency Forum on Child and Family Statistics.*

6-601. The Director of the OMB ("Director") shall convene an Interagency Forum on Child and Family Statistics ("Forum"), which will include representatives from the appropriate Federal statistics and research agencies. The Forum shall produce an annual compendium ("Report") of the most important indicators of the well-being of the Nation's children.

6-602. The Forum shall determine the indicators to be included in each Report and identify the sources of data to be used for each indicator. The



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Forum shall provide an ongoing review of Federal collection and dissemination of data on children and families, and shall make recommendations to improve the coverage and coordination of data collection and to reduce duplication and overlap.

6-603. The Report shall be published by the Forum in collaboration with the National Institute of Child Health and Human Development. The Forum shall present the first annual Report to the President, through the Director, by July 31, 1997. The Report shall be submitted annually thereafter, using the most recently available data.

Sec. 7. *General Provisions.*

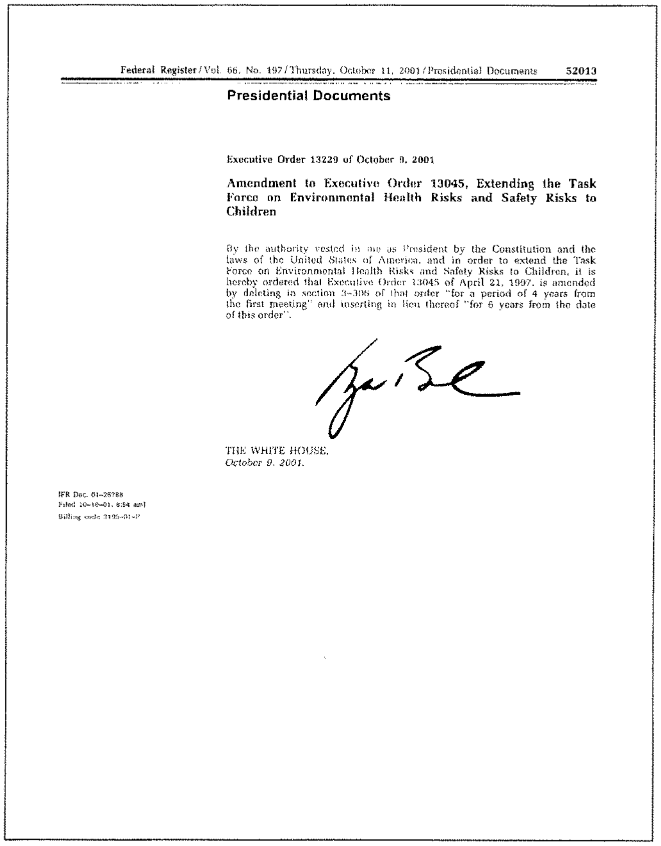
7-701. This order is intended only for internal management of the executive branch. This order is not intended, and should not be construed to create, any right, benefit, or trust responsibility, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies, its officers, or its employees. This order shall not be construed to create any right to judicial review involving the compliance or noncompliance with this order by the United States, its agencies, its officers, or any other person.

7-702. Executive Order 12606 of September 2, 1987 is revoked.

William J Clinton

THE WHITE HOUSE,
April 21, 1997.

[FR Doc. 97-10695
Filed 4-22-97; 8:49 am]
Billing code 3195-01-P



Federal Register / Vol. 66, No. 197 / Thursday, October 11, 2001 / Presidential Documents 52013

Presidential Documents

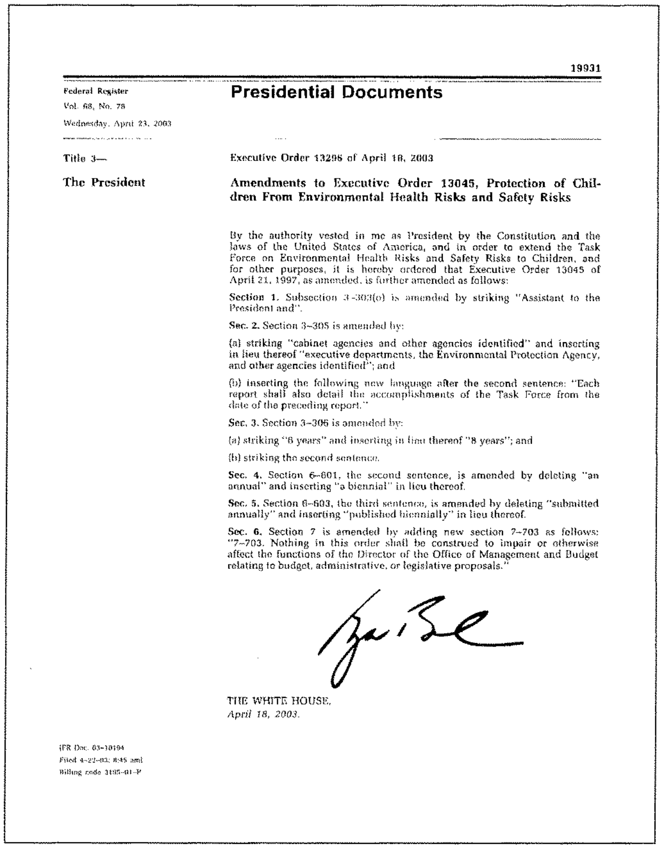
Executive Order 13229 of October 9, 2001

Amendment to Executive Order 13045, Extending the Task Force on Environmental Health Risks and Safety Risks to Children

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to extend the Task Force on Environmental Health Risks and Safety Risks to Children, it is hereby ordered that Executive Order 13045 of April 21, 1997, is amended by deleting in section 3-306 of that order "for a period of 4 years from the first meeting" and inserting in lieu thereof "for 6 years from the date of this order".

THE WHITE HOUSE,
October 9, 2001.

[FR Doc. 01-25788
Filed 10-10-01; 8:54 am]
Billing code 3195-01-P



Federal Register
Vol. 68, No. 78
Wednesday, April 23, 2003

Presidential Documents

Title 3—

The President

Executive Order 13296 of April 18, 2003

Amendments to Executive Order 13045, Protection of Children From Environmental Health Risks and Safety Risks

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to extend the Task Force on Environmental Health Risks and Safety Risks to Children, and for other purposes, it is hereby ordered that Executive Order 13045 of April 21, 1997, as amended, is further amended as follows:

Section 1. Subsection 3-303(o) is amended by striking "Assistant to the President and".

Sec. 2. Section 3–305 is amended by:

(a) striking "cabinet agencies and other agencies identified" and inserting in lieu thereof "executive departments, the Environmental Protection Agency, and other agencies identified"; and

(b) inserting the following new language after the second sentence: "Each report shall also detail the accomplishments of the Task Force from the date of the preceding report."

Sec. 3. Section 3–306 is amended by:

(a) striking "6 years" and inserting in lieu thereof "8 years"; and

(b) striking the second sentence.

Sec. 4. Section 6–601, the second sentence, is amended by deleting "an annual" and inserting "a biennial" in lieu thereof.

Sec. 5. Section 6–603, the third sentence, is amended by deleting "submitted annually" and inserting "published biennially" in lieu thereof.

Sec. 6. Section 7 is amended by adding new section 7–703 as follows: "7–703. Nothing in this order shall be construed to impair or otherwise affect the functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals."

THE WHITE HOUSE,
April 18, 2003.

[FR Doc. 03-10194
Filed 4-22-03; 8:45 am]
Billing code 3195-01-P

Appendix IV: EPA Regulations Subject to Executive Order 13045

Executive Order 13045—Protection of Children from Environmental Health Risks and Safety Risks (Executive Order)—requires that federal agencies provide, to the Office of Management and Budget (OMB) and in the public record, (1) an evaluation of the environmental health or safety effects of the planned regulation on children, and (2) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.[1] Table 6 summarizes the *Federal Register* notice preamble section pertaining to the Executive Order for each of the EPA regulations subject to the Executive Order. The table's columns show (1) the office that initiated the rulemaking; (2) whether a given regulation was final or proposed, and its *Federal Register* citation; (3) the children's environmental health concern(s) EPA identified; and (4 and 5) summaries of how EPA described, in the preamble, its analyses pursuant to the two regulatory requirements of the Executive Order. The table indicates with an arrow (➔) when EPA explicitly directed readers to additional information in the body of the rulemaking or the public docket. The table also indicates with a star (★) when EPA either quantified the effects on children of the regulation or other regulatory options, or explained why it did not do so.

We identified 17 rulemakings since 1998 that EPA determined were subject to the Executive Order's requirements. For each of those regulations, we analyzed whether and how EPA discussed how it met the order's requirements in the notice's preamble. We found that EPA has not consistently documented therein how its rulemakings considered children's environmental health risks. Specifically, we found that, for only 4 of the rulemakings did EPA either quantify the effects of the rulemaking on children or explain why it did not, or could not, do so. For 8 of the rulemakings, EPA explicitly directed the reader—with varying degrees of specificity—to additional information about the regulation's effect on children.

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[1] These requirements are provided in Executive Order 13045 section 501(a) and 501(b), respectively.

Table 6: EPA Regulations Subject to Executive Order 13045

	EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
1	**National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule**				
	Water	Final 71 Fed. Reg. 654 (Jan. 5, 2006).	Cryptosporidiosis from exposure to Cryptosporidium in drinking water. Common symptoms include diarrhea and vomiting. EPA described studies on children's unique susceptibilities and exposures to Cryptosporidium and analyzed data on the number of Cryptosporidium cases in 1999, by age.	EPA stated that the planned regulation will reduce the risk of illness for the entire population, including children. Because children may be disproportionately affected, the regulation may result in greater risk reduction for children. Existing data are not adequate to assess children's risks.	EPA briefly described other regulatory options it considered and stated that the planned regulation was selected because it was deemed feasible and provided significant public health benefits in terms of avoided illnesses and deaths. EPA's analysis indicated that the planned regulation ranks highly among those evaluated with respect to maximizing net benefits.
			→	→ ★	→
		Proposed 68 Fed. Reg. 47,640 (Aug. 11, 2003).	Same	Same	Same
			→	→ ★	→
2	**National Pollutant Discharge Elimination System Permit Regulation and Effluent Limitation Guidelines and Standards for Concentrated Animal Feeding Operations (CAFO)**				
	Water	Final 68 Fed. Reg. 7,176 (Feb. 12, 2003).	Infants under 6 months may be at risk of methemoglobinemia from exposure to nitrates in private drinking-water wells.	EPA estimated that 112,000 households would have their nitrate levels brought to levels that are safe for infants. EPA did not have information on the number of infants living in those households.	EPA estimated that more stringent options would provide only small changes in pollutant loadings to groundwater, such that more stringent options would not provide meaningful protection of children's health risks from methemoglobinemia.
			→	→ ★	→

	EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
		Proposed 66 Fed. Reg. 2,960 (Jan. 12, 2001).	Same In addition, EPA stated that information was not available on the actual number of cases of methemoglobinemia. Furthermore, EPA noted that the following pollutants may also have a disproportionate risk to children: pathogens; trace metals such as zinc, arsenic, copper, and selenium; pesticides; hormones; and endocrine disruptors. However, EPA did not have adequate information to assess the risks to children. →	EPA estimated the number of households that would have their nitrate levels brought to levels that are safe for infants at 166,000 households under the two-tier structure; and 161,000 households under the three-tier structure. → ★	Same →
3	**National Ambient Air Quality Standards for Lead**				
	Air and Radiation	Final 73 Fed. Reg. 66,964 (Nov. 12, 2008).	Neurological effects from childhood exposure to lead. →	EPA stated that the standards were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protection offered by the standards may be especially important for children.	Not explicitly addressed
		Proposed 73 Fed. Reg. 29,184 (May 20, 2008).	Same →	Same	Same
4	**Control of Emissions of Air Pollution From Locomotive Engines and Marine Compression-Ignition Engines Less Than 30 Liters per Cylinder**[a]				
	Air and Radiation	Final 73 Fed. Reg. 25,098 (May 6, 2008).	Not specified EPA stated that children appeared to be overrepresented for some individual facilities, based on initial screening conducted by the agency and described in this section. →	EPA stated that the rulemaking would achieve significant reductions of various emissions from locomotive and marine diesel engines, and that the regulation would benefit children. →	EPA stated that it had evaluated several regulatory strategies and selected the most stringent and effective control reasonably feasible, in light of the technology and cost requirements of the Clean Air Act.

	EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
5	**National Ambient Air Quality Standards for Ozone**				
	Air and Radiation	Final 73 Fed. Reg. 16,436 (Mar. 27, 2008).	Not specified →	Not explicitly addressed	Not explicitly addressed
		Proposed 72 Fed. Reg. 37,818 (Jul. 11, 2007).	Same →	EPA stated that the standards were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protection offered by the standards may be especially important for children.	Same
6	**Control of Hazardous Air Pollutants From Mobile Sources**				
	Air and Radiation	Final 72 Fed. Reg. 8,428 (Feb. 26, 2007).	Cancer and respiratory problems from exposure to hazardous air pollutants from mobile sources, including particulate matter. →	Not explicitly addressed	Not explicitly addressed
		Proposed 71 Fed. Reg. 15,804 (Mar. 29, 2006).	Same →	EPA stated that the regulation may have a disproportionately beneficial effect on children.	Same
7	**Clean Air Fine Particle Implementation Rule**[b]				
	Air and Radiation	Final 72 Fed. Reg. 20,586 (Apr. 25, 2007).	Not specified →	EPA stated that the standards implemented the previously promulgated National Ambient Air Quality Standards (NAAQS) for fine particulate matter, which were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protections offered by the standards may be especially important for children.	Not explicitly addressed

	EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
8	**National Ambient Air Quality Standards for Particulate Matter**				
	Air and Radiation	Final 71 Fed. Reg. 61,144 (Oct. 17, 2006).	Not specified →	EPA stated that the standards were designed to protect public health with an adequate margin of safety, as required by the Clean Air Act, and that the protection offered by the standards may be especially important for children.	Not explicitly addressed
		Proposed 71 Fed. Reg. 2,620 (Jan. 17, 2006).	Same →	Same	Same
9	**Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units**				
	Air and Radiation	Final 70 Fed. Reg. 28,606 (May 18, 2005).	Neurodevelopmental effects to developing fetuses from exposure to methylmercury. →	EPA stated that the regulation would help reduce exposure of women of childbearing age to methylmercury, and estimated the number of children who will be exposed to methylmercury in 2020. EPA estimated how IQ decrements would be reduced as a result of the regulation. EPA also discussed limitations of the regulation to affect human health. → ★	EPA stated the selected option delivered about the same amount of benefits as other regulatory alternatives it considered, but at a lower cost.
		Proposed 69 Fed. Reg. 4,652 (Jan. 30, 2004).	Not specified	EPA stated that the strategies proposed in this rulemaking would improve air quality and children's health.	Not explicitly addressed →
10	**Revision of December 2000 Clean Air Act Section 112(n) Finding Regarding Electric Utility Steam Generating Units; and Standards of Performance for New and Existing Electric Utility Steam Generating Units: Reconsideration**[c]				
	Air and Radiation	Final 71 Fed. Reg. 33,388 (Jun. 9, 2006).	Not specified	EPA explained that it had evaluated the environmental health or safety effects to children of its Clean Air Mercury Rule. →	Not explicitly addressed

	EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
11	**Control of Air Pollution from New Motor Vehicles: Heavy-Duty Engine and Vehicle Standards and Highway Diesel Fuel Sulfur Control Requirements**				
	Air and Radiation	Final 66 Fed. Reg. 5,002 (Jan. 18, 2001).	Not specified EPA noted that some of pollutants addressed in the regulation may disproportionately affect children's health, such as ozone, particulate matter and certain toxic air pollutants. →	EPA stated that the rulemaking would reduce air toxics and the related impacts on children's health. Explained that EPA had addressed the effect on children of exposure to ozone and particulate matter in its rulemakings to establish the NAAQS for those pollutants, and that it was not revisiting those here. →	EPA stated that, consistent with the Clean Air Act, the planned regulation was designed to achieve the greatest degree of reduction of emissions achievable through available technology, taking cost and other factors into consideration. →
		Proposed 65 Fed. Reg. 35,430 (June 2, 2000).	Same →	Same →	Same →
12	**Control of Emissions of Air Pollution from 2004 and Later Model Year Heavy-Duty Highway Engines and Vehicles; Revision of Light-Duty On-Board Diagnostics Requirements**				
	Air and Radiation	Final 65 Fed. Reg. 59,896 (Oct. 6, 2000).	Not specified EPA noted that some pollutants addressed in the regulation may disproportionately affect children's health, such as ozone, particulate matter and certain toxic air pollutants. →	EPA stated that the rulemaking would reduce air toxics and the related impacts on children's health. Explained that EPA had addressed the effect on children of exposure to ozone and particulate matter in its rulemakings to establish the NAAQS for those pollutants, and that it was not revisiting those here. →	EPA stated that, consistent with the Clean Air Act, the planned regulation was designed to achieve the greatest degree of reduction of emissions achievable through available technology, taking cost and other factors into consideration. →
		Proposed 64 Fed. Reg. 58,472 (Oct. 29, 1999).	Same →	Same →	Same →

	EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
13	**Control of Air Pollution From New Motor Vehicles: Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements**				
	Air and Radiation	Final 65 Fed. Reg. 6,698 (Feb. 10, 2000).	Not specified EPA noted that some of pollutants addressed in the regulation may disproportionately affect children's health, such as ozone, particulate matter and certain toxic air pollutants. ➜	EPA stated that the rulemaking would reduce air toxics and the related impacts on children's health. Explained that EPA had addressed the effect on children of exposure to ozone and particulate matter in its rulemakings to establish the NAAQS for those pollutants, and that it was not revisiting those here. ➜	EPA stated that the planned regulation was the most stringent and effective control reasonably feasible at the time, in light of the technology and cost requirements of the Clean Air Act. ➜
		Proposed 64 Fed. Reg. 26,004 (May 13, 1999).	Same ➜	Same ➜	Same ➜
14	**Lead; Renovation, Repair, and Painting Program**				
	Prevention, Pesticides, and Toxic Substances	Final 73 Fed. Reg. 21,692 (Apr. 22, 2008).	Not specified ➜	EPA stated that the primary purpose of the regulation was to minimize exposure in children under age 6 to lead-based paint hazards created during renovation, repair, and painting activities in housing or other buildings. Estimated that the regulation would affect 1.4 million children under age 6, providing considerable benefits to those children. ★	Not explicitly addressed
		Proposed 71 Fed. Reg. 1,588 (Jan. 10, 2006).	Same ➜	EPA stated that one purpose of the proposed regulation was to prevent the creation of new lead-based paint hazards from housing where children under age 6 reside. Estimated that the regulation would affect 1.1 million children under age 6, providing considerable benefits to those children. ★	Same

	EPA office	Type of regulation (date)	Children's environmental health concern	Effect on children of planned regulation	Why regulation is preferable to other options
15	**Lead and Lead Compounds; Lowering of Reporting Thresholds; Community Right-to-Know Toxic Chemical Release Reporting**				
	Prevention, Pesticides, and Toxic Substances	Final 66 Fed. Reg. 4,500 (Jan. 17, 2001).	Not specified EPA stated that it identified and assessed the environmental health risks and safety risks that may disproportionately affect children.	EPA described how the informational benefits of the planned regulation could positively impact children and other populations.	Not explicitly addressed
		Proposed 64 Fed. Reg. 42,222 (Aug. 3, 1999).	Same	Same	Same
16	**Lead; Identification of Dangerous Levels of Lead**				
	Prevention, Pesticides, and Toxic Substances	Final 66 Fed. Reg. 1,206 (Jan. 5, 2001).	Not specified →	EPA stated that the selected standards were designed first and foremost to protect children from lead in residential paint, dust, and soil.	EPA stated that it could have selected numerically more stringent standards, but concluded that they would provide less protection to children because limited resources would be diluted and possibly diverted away from children at greatest risk.
		Proposed 63 Fed. Reg. 30,302 (Jun. 3, 1998).	Same →	EPA stated that young children were the primary beneficiaries of the proposed regulation because exposure to lead, paint, and dust is mostly limited to children under the age of 6.	Not explicitly addressed
17	**Persistent Bioaccumulative Toxic (PBT) Chemicals; Lowering of Reporting Thresholds for Certain PBT Chemicals; Addition of Certain PBT Chemicals; Community Right-to-Know Toxic Chemical Reporting**				
	Prevention, Pesticides, and Toxic Substances	Final 64 Fed. Reg. 58,666 (Oct. 29, 1999).	Not explicitly addressed	EPA described how the informational benefits of the rule could positively impact children and other populations.	Not explicitly addressed
		Proposed 64 Fed. Reg. 688 (Jan. 5, 1999).	Same	Same	Same

Source: GAO analysis of *Federal Register* notices' preamble sections.

Notes:

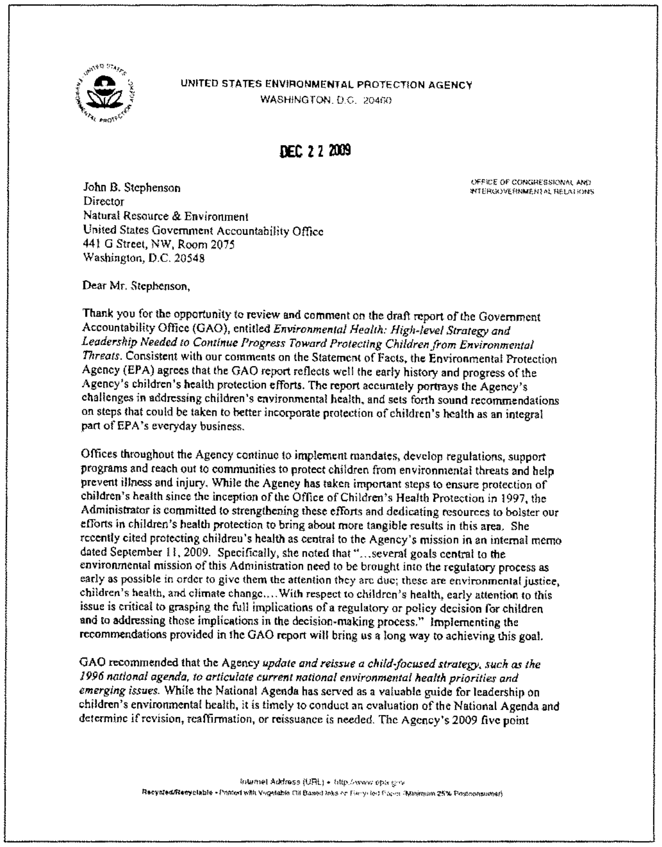
The table indicates with an arrow (→) when EPA explicitly directed readers to additional information in the body of the rulemaking or the public docket. The table also indicates with a star (★) when EPA either quantified the effects on children of the regulation or other regulatory options, or explained why it did not do so.

[a] EPA determined that the proposed regulation, published April 3, 2007, was not subject to Executive Order 13045 because the agency did not have reason to believe that the environmental health risks or safety risks addressed by the regulation presented a disproportionate risk to children.

[b] EPA determined that the proposed regulation, published November 1, 2005, was not subject to Executive Order 13045. EPA did not explicitly state in its *Federal Register* notice why the regulation was not subject to the order.

[c] This regulation sets forth EPA's decision after reconsidering certain aspects of the March 29, 2005, final rule entitled "Revision of December 2000 Regulatory Finding on the Emissions of Hazardous Air Pollutants From Electric Utility Steam Generating Units and the Removal of Coal- and Oil-Fired Electric Utility Steam Generating Units from the Section 112(c) List" (Section 112(n) Revision Rule). The regulation also includes EPA's final decision regarding reconsideration of certain issues in the May 18, 2005, final rule entitled "Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units" (Clean Air Mercury Rule; CAMR), which was subject to Executive Order 13045.

Appendix V: Comments from the Environmental Protection Agency



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 22 2009

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

John B. Stephenson
Director
Natural Resource & Environment
United States Government Accountability Office
441 G Street, NW, Room 2075
Washington, D.C. 20548

Dear Mr. Stephenson,

Thank you for the opportunity to review and comment on the draft report of the Government Accountability Office (GAO), entitled *Environmental Health: High-level Strategy and Leadership Needed to Continue Progress Toward Protecting Children from Environmental Threats*. Consistent with our comments on the Statement of Facts, the Environmental Protection Agency (EPA) agrees that the GAO report reflects well the early history and progress of the Agency's children's health protection efforts. The report accurately portrays the Agency's challenges in addressing children's environmental health, and sets forth sound recommendations on steps that could be taken to better incorporate protection of children's health as an integral part of EPA's everyday business.

Offices throughout the Agency continue to implement mandates, develop regulations, support programs and reach out to communities to protect children from environmental threats and help prevent illness and injury. While the Agency has taken important steps to ensure protection of children's health since the inception of the Office of Children's Health Protection in 1997, the Administrator is committed to strengthening these efforts and dedicating resources to bolster our efforts in children's health protection to bring about more tangible results in this area. She recently cited protecting children's health as central to the Agency's mission in an internal memo dated September 11, 2009. Specifically, she noted that "...several goals central to the environmental mission of this Administration need to be brought into the regulatory process as early as possible in order to give them the attention they are due; these are environmental justice, children's health, and climate change....With respect to children's health, early attention to this issue is critical to grasping the full implications of a regulatory or policy decision for children and to addressing those implications in the decision-making process." Implementing the recommendations provided in the GAO report will bring us a long way to achieving this goal.

GAO recommended that the Agency *update and reissue a child-focused strategy, such as the 1996 national agenda, to articulate current national environmental health priorities and emerging issues*. While the National Agenda has served as a valuable guide for leadership on children's environmental health, it is timely to conduct an evaluation of the National Agenda and determine if revision, reaffirmation, or reissuance is needed. The Agency's 2009 five point

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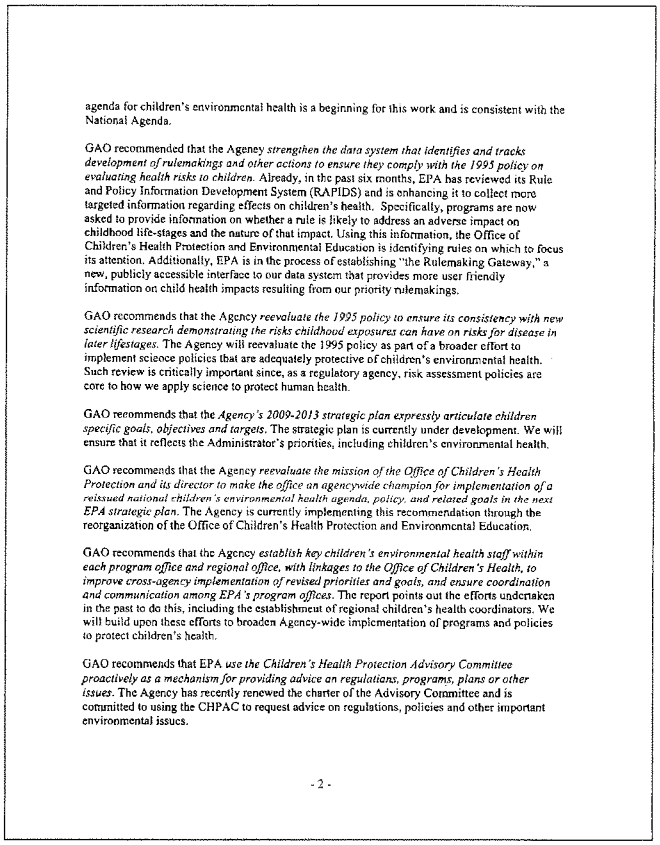


agenda for children's environmental health is a beginning for this work and is consistent with the National Agenda.

GAO recommended that the Agency *strengthen the data system that identifies and tracks development of rulemakings and other actions to ensure they comply with the 1995 policy on evaluating health risks to children.* Already, in the past six months, EPA has reviewed its Rule and Policy Information Development System (RAPIDS) and is enhancing it to collect more targeted information regarding effects on children's health. Specifically, programs are now asked to provide information on whether a rule is likely to address an adverse impact on childhood life-stages and the nature of that impact. Using this information, the Office of Children's Health Protection and Environmental Education is identifying rules on which to focus its attention. Additionally, EPA is in the process of establishing "the Rulemaking Gateway," a new, publicly accessible interface to our data system that provides more user friendly information on child health impacts resulting from our priority rulemakings.

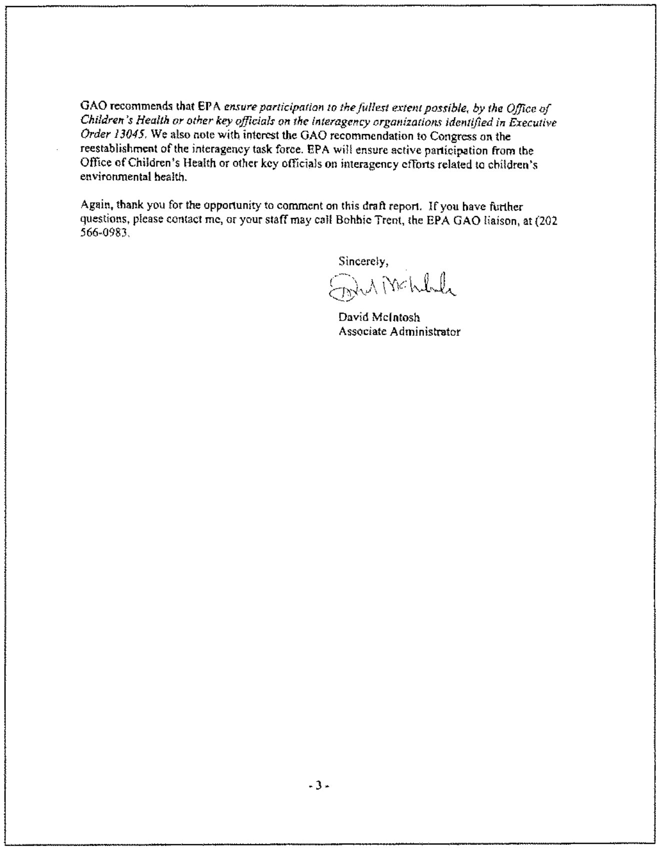
GAO recommends that the Agency *reevaluate the 1995 policy to ensure its consistency with new scientific research demonstrating the risks childhood exposures can have on risks for disease in later lifestages.* The Agency will reevaluate the 1995 policy as part of a broader effort to implement science policies that are adequately protective of children's environmental health. Such review is critically important since, as a regulatory agency, risk assessment policies are core to how we apply science to protect human health.

GAO recommends that the *Agency's 2009-2013 strategic plan expressly articulate children specific goals, objectives and targets.* The strategic plan is currently under development. We will ensure that it reflects the Administrator's priorities, including children's environmental health.

GAO recommends that the Agency *reevaluate the mission of the Office of Children's Health Protection and its director to make the office an agencywide champion for implementation of a reissued national children's environmental health agenda, policy, and related goals in the next EPA strategic plan.* The Agency is currently implementing this recommendation through the reorganization of the Office of Children's Health Protection and Environmental Education.

GAO recommends that the Agency *establish key children's environmental health staff within each program office and regional office, with linkages to the Office of Children's Health, to improve cross-agency implementation of revised priorities and goals, and ensure coordination and communication among EPA's program offices.* The report points out the efforts undertaken in the past to do this, including the establishment of regional children's health coordinators. We will build upon these efforts to broaden Agency-wide implementation of programs and policies to protect children's health.

GAO recommends that EPA *use the Children's Health Protection Advisory Committee proactively as a mechanism for providing advice on regulations, programs, plans or other issues.* The Agency has recently renewed the charter of the Advisory Committee and is committed to using the CHPAC to request advice on regulations, policies and other important environmental issues.



GAO recommends that EPA *ensure participation to the fullest extent possible, by the Office of Children's Health or other key officials on the interagency organizations identified in Executive Order 13045.* We also note with interest the GAO recommendation to Congress on the reestablishment of the interagency task force. EPA will ensure active participation from the Office of Children's Health or other key officials on interagency efforts related to children's environmental health.

Again, thank you for the opportunity to comment on this draft report. If you have further questions, please contact me, or your staff may call Bohhie Trent, the EPA GAO liaison, at (202 566-0983.

Sincerely,

David McIntosh
Associate Administrator

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

John Stephenson, (202) 512-3841 or stephensonj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Diane Raynes, Assistant Director; Elizabeth Beardsley; Timothy Bober; Mark Braza; Emily Hanawalt; Terrance Horner, Jr.; Aaron Shiffrin; Benjamin Shouse; and Kiki Theodoropoulos made key contributions to this report.

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